EXHIBIT 2E

WAVE 1

EXHIBIT

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IN RE: PELVIC MESH/GYNECARE LITIGATION	:SUPERIOR COURT OF :NEW JERSEY :LAW DIVISION - :ATLANTIC COUNTY : :MASTER CASE 6341-10 : :CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

- - -

October 23, 2012

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Transcript of the continued deposition of PROF. DR. MED. UWE KLINGE, called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure by and before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Certified Court Reporter, and Notary Public for the State of New Jersey, at the Quellenhof Hotel, Monheimsallee 52 52062 Aachen, Germany, commencing at 9:04 a.m.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.951.5672 fax
deps@golkow.com

APPEARANCES:

ANDERSON LAW OFFICES, LLC
BY: BENJAMIN HOUSTON ANDERSON, ESQUIRE
1360 West 9th Street
Suite 215
Cleveland, Ohio 44113
(216) 592-8384
ben@andersonlawoffices.net

THE RESTAINO LAW FIRM
BY: JOHN M. RESTAINO, DPM, MPH, ESQUIRE
1550 Larimer Street, Suite 527
Denver, Colorado 80202
(720) 924-2006
jrestaino@restainolawfirm.com
Representing the Plaintiffs

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC
BY: MICHAEL L. BROWN, ESQUIRE
1020 Highland Colony Parkway
Suite 1400
Ridgeland, Mississippi 39157
(601) 948-5711
michael.brown@butlersnow.com
Representing Johnson & Johnson and Ethicon

THOMAS COMBS & SPANN, PLLC
BY: DAVID B. THOMAS, ESQUIRE
300 Summers Street
Suite 1380
Charleston, West Virginia 25301
dthomas@tcspllc.com
Representing Johnson & Johnson and Ethicon

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(Deposition Exhibit No. Klinge-12, Letter dated October 17, 2012, was marked for identification.)

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PROF. DR. UWE KLINGE, after having been previously duly sworn, continued to be examined and testified as follows:

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EXAMINATION

- - -

BY MR. BROWN:

Q. Good to see you this morning.

During the times that you were being funded by Ethicon up until 2005, who were some of your major contacts at Ethicon, people you spoke to regularly?

A. It has been the head of the R&D department at Norderstedt, Dr. Hoepfner, H-O-E-P-F-N-E-R, Dr. Hoepfner, and his successor was Dr. Engel, E-N-G-E-L. And with his team. It was Dr. Walte, W-A-L-T-E. It was Dr. Holste, Dr. Hellhammer, Dr. Batke later on, sometimes Frau Schuldt, S-C-H-U-L-D-T, E, I'm not sure. These are the people that came four times a year to Aachen to

discuss this.

Q. Now, Doctor, for the materials that you have that you relied upon to write your report, do you maintain those in a hard copy or on your computer?

A. Please?

Q. Sure.

The documents that you work with to help write your expert report, do you keep them on your computer or do you have them just in a stack of documents like this?

A. Most of my documents are on the computer.

Q. Okay.

A. There are some others from books that are as a hard copy there.

Q. And do you highlight on the hard copies? Do you take a highlighter and highlight or write on the hard copies?

A. No.

Q. Do you make notes? Do you write on the documents?

A. On the hard copies?

Q. Yes.

A. Whether I made it? Usually not.

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Q. Does that mean sometimes you do or --
A. I think in some few instances I made some remarks to the hard copies, but...
Q. And, Doctor, when you keep up with your time to send your counsel for payment, do you keep up with hour by hour what you did?
A. It is a list of hours per week, which I will -- or of the hours I spent for working on this topic.
Q. And then you would send those hours to your counsel for payment for your work; is that right?
A. After some time, I collected it, and then I sent them.
Q. Doctor, everything that you've relied on to write your expert report, is it identified in your expert report? And plaintiffs' counsel has given me quite a number of additional documents that I believe he's provided to you.
So based upon what you've cited -- let me just state this.
Your counsel, plaintiffs' counsel, has given us an additional list of materials that he's provided to you to review; is that correct?
MR. ANDERSON: Since his expert

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report.
BY MR. BROWN:
Q. Since your expert report; is that right?
A. That he provided you a list?
Q. No, no.
A. That is right. Maybe.
Q. No, no.
I'm saying that since you wrote your expert report, you remember Dr. Williams wrote a report. Right?
A. Yes.
Q. And so your counsel gave you Dr. Williams' report so you could review his report. Right?
A. That is right.
Q. And then he gave you a couple other reports and documents; is that right?
A. That is right.
Q. And from what your counsel has given you and what you've put in your expert report, is that all the materials that you've used to rely upon to write your expert report?
MR. ANDERSON: Objection.
Go ahead.

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THE WITNESS: As this expert report is based on all what we have learned and done and experienced, I think it is -- or it is not possible to put all this knowledge into this expert report. Otherwise, it would have been thousands of pages there. So, of course, this is an extract with the references that are important to underline this. But there are lots of others as well that are not -- I have to admit that are not listed in this.
BY MR. BROWN:
Q. Are there other studies that you are aware of that you used to write your report that aren't identified in your expert report?
A. I'm not aware of some -- or the intention for this expert report was to explain my opinions. And, therefore, I needed or I added some references which I think made it very clear why I came to this conclusion. Of course, usually there are lots of others that confirm this as well. So, therefore, it is a selection of references, of course. If -- I've seen so many documents there and I could have added all these documents there.
Q. When you say you've seen all these documents, which documents are you talking about?
A. I have seen a lot of documents from

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Ethicon, a lot of PowerPoint presentations, a lot of drafts, a lot of reports, yeah.
Q. Doctor, as you sit here, though, are there any studies that you know of that support your opinion that you're relying on that you have not put in your expert report?
A. Again, it is a very -- can you please say it again?
Q. Sure, yes. I'm looking for any studies, Doctor, that -- I'll give you an example.
So do you remember when you were -- in your expert report you were talking about degradation in your expert report and you cited your Clave article?
A. Uh-huh.
Q. So you used that study to help support one of your opinions; is that right?
A. Uh-huh.
MR. ANDERSON: Yes?
THE WITNESS: Yes. Sorry.
BY MR. BROWN:
Q. No problem.
Are there other studies like that that support your opinions that you didn't put in your expert report?

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MR. ANDERSON: Or that aren't listed here?
BY MR. BROWN:
Q. Or that aren't listed here. And when I say "here," on Exhibit 12. That you're aware of, Doctor.
A. Let me answer with another example.
If you take the term "biocompatibility," I did not include all possible references for this term in my reference report. It was just a selection.
Q. Doctor, is it fair to say, is there any other studies that you would need to cite to, to support your opinions in your expert report that aren't in your report or aren't in Exhibit 12?
A. I didn't -- please --
Q. What I want to do is just make sure if there's other studies out there, that I have an opportunity to look at them so that I can see what you're basing your opinions on.
And so all I want to know is, are there any other studies out there that you're primarily using to support your opinions on your expert report that aren't in your expert report or that are not in this Exhibit 12?

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A. So as you said, primarily used, I don't -- I think, or to my opinion, there is no other report that is necessary to review to follow these opinions.
Q. Okay.
MR. ANDERSON: I wanted to wait until he answered and not interrupt you, but I'm just going to place an objection just in terms of, as you are aware, there's been this rolling production of documents. And we're still awaiting a lot of documents. And so if anything comes into the documents that's been produced that we haven't fairly had a chance to look at and he hasn't had a chance to consider, we would, of course, look at those, have him consider them. And if it's going to change or buttress his opinions or something that appears that would be unfair for us to come to trial and all of a sudden hand to him, I will give you my word that we will -- I will send you an e-mail and I will say, these are the documents that came in, I've provided them to Dr. Klinge, and he's going to base part of his opinions on those documents, in all fairness to me and to you.
MR. BROWN: That's fine.
MR. THOMAS: At that point, will you

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give us an opportunity to ask him questions?
MR. ANDERSON: I think that would only be fair, so the answer is yes. Maybe it's a video conference depo.
MR. THOMAS: Thank you.
We can work out the details.
MR. ANDERSON: We can work out the details, but that would only be fair.
BY MR. BROWN:
Q. Doctor, moving on.
I think yesterday you had told me that you and Dr. Klosterhalfen were working on a publication now together; is that right?
A. That is right.
Q. Can you tell me what's the study on? What are you studying? Maybe it's easier to say this: What's the purpose of the study?
A. In the moment, we have three projects together. First is a -- we were invited to make a manuscript or with a title the ideal mesh for, I think the journal's name is Biology, part of Physiology.
Q. I'm sorry, go ahead.
A. And the manuscript is, in the moment, in the review by Bernd Klosterhalfen.

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The second was that we are working on the evaluation of 1,000 explanted hernia meshes, the histological evaluation and the presentation of the data and the interpretation. And that is summarized in a manuscript which we recently submitted.
And the third activity, main activity, is that, in the moment, we are trying to identify the cells of the inflammatory infiltrate of human explanted meshes by performing immunohistochemistry, serous red staining, and I hope the next time we can perform double fluorescent immunohistochemistry to identify which cells are responsible for the chronic inflammatory reaction of the foreign body, because this is not clear from the scientific point. So these are the three activities we actually have together.
Q. Doctor, on the publication talking about identifying the ideal mesh, are y'all actually describing the characteristics of what an ideal mesh looks like?
A. In this manuscript we gave our idea how to answer this question, first of all, that there -- so shortly, I can give you a short summary of what is in. The basic idea is that there is no one ideal mesh, that you have to consider the

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functional requirements for this, that you have to consider structural requirements, that you have to look at the tissue ingrowth, that you have to consider the location, that you have to consider the size of the configuration, that you have to consider, of course, the polymer, that you have to consider the porosity, the pore structures. All this together helps to get an understanding and to find the optimum solution for a specific indication. That is briefly what we want to outline in this text.

Q. And, Doctor, is this study with regard to finding a mesh for hernia repair?

A. This is not specific. It is dealing with textile structures in surgery.

Q. So if I hear you right, you're not saying that there is one construction right for every particular issue; is that right?

MR. ANDERSON: Objection to form.

Go ahead.

BY MR. BROWN:

Q. Let me restate that.

Are you saying that there is not one particular way to design a mesh that will fit every patient's needs?

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A. The idea one fits all, it doesn't work.

Q. I understand.

Now, Doctor, as far as the second article --

Doctor, do you have a copy of that article?

A. I cannot make a copy. It is a draft only on the computer in the moment, so, but... And I'm not sure whether something will be changed during the next days, but I have a draft now.

Q. Doctor, let me ask you, too, on the -- you say the evolution of the 1,000 explanted hernia meshes.

MR. ANDERSON: He said evolution or evaluation?

MR. BROWN: Was it evaluation? I'm sorry.

THE WITNESS: Evaluation.

BY MR. BROWN:

Q. Evaluation.

So on the article, the evaluation of 1,000 explanted hernia meshes, where is the data for this 1,000 explanted hernia meshes?

MR. ANDERSON: Objection.

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Go ahead.

Do you understand?

THE WITNESS: Where are the data?

BY MR. BROWN:

Q. Yes.

Let me restate it then.

These 1,000 explanted meshes, were they sent to Dr. Klosterhalfen?

A. Yes.

Q. And then did Dr. Klosterhalfen review each one of these explanted meshes from a pathology standpoint?

A. I don't know what is a pathology standpoint. I know he's a pathologist, and he has an experience and he has written a protocol to look at these meshes, which is far beyond the standard evaluation of some tissues. So he followed this protocol and he made an analysis of these 1,000 explanted meshes.

Q. Now, his evaluation of those 1,000 meshes, where are those evaluations?

MR. ANDERSON: Objection.

THE WITNESS: On a hard disk.

BY MR. BROWN:

Q. Is this a hard disk with your group

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at Aachen?

MR. ANDERSON: He's trying to find out physically where this information is stored from which you are able to -- that he took this and you took this analysis from. So he wants to know, is that stored on a computer at Aachen? Is it in Duren? Where is that information?

THE WITNESS: In the moment, these files that can be evaluated are on the computer of Professor Klosterhalfen and on my personal computer. So we have access. We have access to the -- we both have access to these data.

BY MR. BROWN:

Q. That's exactly what I was looking for. Thanks for that.

And those are documents you can provide to your counsel, is that right, the evaluations?

MR. ANDERSON: Can you share that data with me?

THE WITNESS: I have to ask Professor Klosterhalfen.

BY MR. BROWN:

Q. Doctor, let's move to a different study, which is you were telling me yesterday about

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a study with PVDF being compared to polypropylene where you reviewed the article.
Do you remember that?
A. Which -- we have done several articles with PVDF, and so which one do you --
Q. I think you were saying that there was a study comparing polypropylene and PVDF that has not been published yet that you were a reviewer for; is that right?
MR. ANDERSON: Dr. Kirschner-Herrmans.
THE WITNESS: The ultrasound investigation of the -- yeah.
BY MR. BROWN:
Q. Is that the study that compares PVDF and polypropylene?
A. Yes.
Q. In humans?
A. They compared it in humans. It was an investigation at the continence center at women.
Q. And what were you doing on this article? What was your purpose for reviewing this article?
A. The -- I was charged in explaining them the general reaction of tissue to textile

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implants and to discuss with them the -- whether -- about the balance of the tissue requirements or the tissue characteristics and the differences of the textiles, how to characterize the textiles, how to make an analysis of the data, how to make figures for the data, how to perform the statistics of these data. And we are all together discussing the interpretation of these findings.
Q. Are you writing some of this article?
A. I contributed with some text in this, of course.
Q. Will you be a co-author on the article?
A. Yeah, yes.
Q. It's very good. Very few people pick that up on their own and actually do that, so you've done well.
Doctor, I'm going to show you Exhibit 10. This is just trying to clarify a couple of things from yesterday as well.
Doctor, if you look on Exhibit 10, what I'm trying to find out in your study is that if you were studying the actual Prolene® Soft Meshes in Prolift®?
So if you'll look on the second page

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on 366, it should be the second page, Doctor, on 366, do you see where there's Group I, Group II and Group III? And it appears, Doctor, that there's three different types of meshes that you were looking at; is that correct? Three different meshes?
A. Give me a minute, please.
Q. Sure.
MR. ANDERSON: Take your time to look as much of the document as you need to.
- - -
(Deposition Exhibit No. Klinge-13, PowerPoint, "GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse," Bates stamped ETH.MESH.00803713, and Deposition Exhibit No. Klinge-14, Article entitled "The biology behind fascial defects and the use of implants in pelvic organ prolapse repair", were marked for identification.)
- - -
BY MR. BROWN:
Q. Doctor, while you're looking, I want to show you two things to see if this helps you

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determine, and you can read as much as you need to as well.
But if I can show you on Exhibit 14 and just see if this helps you. Exhibit 14 is Jan Deprest, and he gives some of the exact parameters of what the Gynemesh® PS, which is the same as Prolene® Soft. And then this is a picture of the Prolene® Soft Mesh as well. And you can see you've got a picture on your third page, and see if that helps you determine if that's the Prolene® Soft that you were assessing in this article.
MR. ANDERSON: There's a list of the meshes on the first page.
THE WITNESS: So, yeah. So from this image and from the data, there seems to be similarity to soft Prolene® mesh. But I don't know whether it is exactly coming from the product taken from this and using this for animals, or whether there is some sort of modification, whether it's for experimental use, provided for Aachen from Hamburg Norderstedt, I don't know it, because I didn't receive these meshes. They were delivered to Joachim Conze as well.
BY MR. BROWN:
Q. Let me ask you --

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A. So, therefore, there obviously are some similarities to these meshes. But whether this is the original soft pro mesh, I don't know and I didn't find it. There is a general introduction here, but it should have been mentioned in the materials and methods section which is the provider of this material.

MR. ANDERSON: It appears that page 1 lists what the groups are.

BY MR. BROWN:

Q. But what I'm trying to find out is, is this the Prolene® Soft Mesh.

A. Yeah, this one. And this one, it is -- I cannot --

MR. ANDERSON: No, no. Group I -- yeah, okay.

BY MR. BROWN:

Q. Doctor, let me ask you this.

If you look at your expert report, I can just show you a copy of mine. If you look at your expert report on porosity on page 25, I think you see where some of the weights for the Prolene® Soft Mesh is 45 grams to 42.7; is that right?

MR. ANDERSON: Is that what's listed here?

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BY MR. BROWN:

Q. Is that what your expert report says?

A. Yes.

Q. And then if you look here, Doctor, at the way --

A. 45 grams.

Q. So it's the same weight as the Prolene® Soft Mesh, is that right, as you studied in your report?

A. This one?

Q. On Exhibit 10. That's correct.

A. This one, this mesh used for group 2 has a weight of 45 grams per square meter, and this is close to these data.

Q. And then, Doctor, if you look, too, at the picture that I've provided you in Exhibit 13, does that appear to have the same type of construction as what's in Exhibit 10?

MR. ANDERSON: Objection.

BY MR. BROWN:

Q. If you look at the picture on page 3?

MR. ANDERSON: Objection.

Go ahead.

BY MR. BROWN:

Q. And I'm looking at the one that says "PP2.5."

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A. This one?

Q. Yes, sir.

A. When I compare these two pictures, I see some similarities with these filaments running through the pores. But, of course, there seem to be some differences as well. So in this, you can identify one, two, three, four filaments going through, and it's hardly possible to find it in here. That cannot exclude that maybe it's the same, but from these images alone, you see some differences as well.

Q. And similar characteristics but some differences; is that right?

A. There are some. Some similarities, but some differences.

Q. And then if you also look, if you'll go back just one page, where it says the mesh pore size on group 2, do you see that, 2.5, is that similar to the pore size on Exhibit 13?

A. It is impossible to -- the mentioning of a pore size was one figure. It is insufficient to reflect all the construction in regard to the pore size. That is to ease the understanding for the reader to give a rough idea, but it is not

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possible to made a comparison because of this single volume.

Q. Doctor, what I'm trying to do is just find out, just because it was your article, if this was the Prolene® Soft. And it sounds like you're saying that there are similar characteristics, but you don't know if that was for sure Prolene® Soft; is that right?

A. That is right.

Q. Okay.

MR. ANDERSON: Did we mark those?

MR. BROWN: Yes.

MR. ANDERSON: So 14 was Deprest, and 15 was the PowerPoint entitled --

MR. BROWN: 13 was the PowerPoint.

MR. ANDERSON: Oh, sorry. 13 was the PowerPoint entitled "Gynecare Gynemesh® PS."

- - -

(Deposition Exhibit No. Klinge-15, Article entitled "Functional and Morphological Evaluation of a Low-Weight, Monofilament Polypropylene Mesh for Hernia Repair", was marked for identification.)

- - -

BY MR. BROWN:

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Q. Doctor, I'm showing you Exhibit 15 now.

This is another study that you were an author on; is that right?

A. That is right.

Q. And this is another paper that I'm trying to find out which mesh you tested.

Do you know if this was the mesh for -- let me ask you to do this first. If you'd look over to page 3 which says 131 on the top right.

Do you see the table, Doctor?

A. Yes, I see it.

Q. For the one that says, under "LW," do you know if that is the Prolene® Soft Mesh that was being studied here?

A. Give me a minute.

Q. Doctor, if it helps you to look at Deprest, you can also look at that as well.

MR. ANDERSON: Take your time and read that as long as you need to.

THE WITNESS: I cannot answer this question.

BY MR. BROWN:

Q. Okay.

A. So I don't see any proof or

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confirmation that this is the soft pro mesh. And if you're looking to Figure 2, where you have this fat tissue in between the filaments, there is no crosslinking or passing filament in there, so this figure does not indicate that this is a soft Prolene® mesh.

Q. Doctor, let me ask you this: On page 131, if you go to the table, for the mesh identified as "LW," does that have the same weight as the Prolene® Soft Mesh?

A. Yes.

Q. And if you look --

A. Similar.

Q. And if you have the filament radius as 47 microns, does that have the same filament radius as the Prolene® Soft? Doctor, I don't want to trick you, so I'm going to see if this helps you with Jan Deprest, with 14.

A. No, no. This is the thickness of the material in millimeter. In Table 1, there is a filament radius in micrometer.

Q. Microns?

A. Microns. So this means the thickness of the material and this means the thickness of the polypropylene filament. And this is then

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94 microns. It's the diameter of this size of this polypropylene filament that is used in this.

Q. Doctor, let me make sure I understand you correctly here.

When Jan Deprest is measuring the thickness, he's measuring the thickness of the fiber; is that correct?

MR. ANDERSON: Objection.

THE WITNESS: Thickness -- give me a minute, I have to look what --

BY MR. BROWN:

Q. Sure.

A. So I don't see any further explanation, but .45 millimeter usually is the thickness of the entire mesh there. This is for most of the meshes in the range of half a millimeter to .7 millimeter. This is tenfold more than the filament radius in micrometers there.

Q. Let me ask you this, Doctor.

A. So you cannot compare these two data. It's completely different.

Q. Is .45 millimeters, is that --

Okay. So you're saying you can't compare those two? Is that what you're saying?

A. Yes. These two are completely

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different properties, characteristics.

Q. Let me ask you this.

Coming back to your article, which is Exhibit 15, on Table 131, the filament radius of the Prolene® Soft, is it around 47 microns approximately?

A. Yeah, yeah. This one has a diameter of 94 microns. And I have to look, it is around 90 microns, the diameter of the Prolene® Soft or the Prolift® mesh. It is around maybe 87 or so. I'm not sure.

Q. Sure. And I'm not asking exactly.

I'm just saying, the filament radius for your study, does that have a similar radius to the Prolene® Soft Mesh?

MR. ANDERSON: Objection.

THE WITNESS: It is -- as I remember, it is 8 microns more in this.

BY MR. BROWN:

Q. Exhibit 15 is 8 microns more than the Prolene® Soft Mesh?

A. If the Prolene® Soft has a diameter of 85 microns, then it is 9 microns more in this table.

Q. Okay. When you look at the pore

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size, when it says greater than 1 millimeter, is the pore size of Prolene® Soft greater than 1 millimeter, on page 131, Doctor?

A. Yes, yes. I just looked to the data where this has been published, and this has been published in 2002. So at that time point, we have a complete different look at pore sizes, porosity, and so -- and, therefore, it stands in this table, but, of course, it does not reflect the complex importance of pore sizes as we know today.

Q. So as of 2002, in your opinion, the pore size of Prolene® Soft would have been characterized as greater than 1 millimeter; is that correct? As of 2002?

A. As --

MR. ANDERSON: Hold on, hold on. Objection, misstates the document.

BY MR. BROWN:

Q. Go ahead and answer the question.

MR. ANDERSON: Misstates -- that's not fair. It doesn't say greater than 1 millimeter.

MR. BROWN: That doesn't have a greater than sign?

MR. ANDERSON: Look over to the left.

MR. BROWN: Pore size --

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MR. ANDERSON: What's it say? What's the value?

MR. BROWN: Millimeter squared.

MR. ANDERSON: Millimeter squared.

BY MR. BROWN:

Q. Doctor, let me ask you this.

A. He's right.

Q. That's fine.

But, Doctor, as far as pore size for the lightweight mesh, is that the same pore size -- let me say it this way.

Does the pore size for the lightweight mesh characterize the Prolene® Soft Mesh as of 2002?

MR. ANDERSON: Objection.

THE WITNESS: First of all, I don't know whether this is a -- the soft -- it is not clear that this is the soft Prolene® mesh in effect or whether it's an experimental thing. So all these statements came from my point of view, not referred directly to the characteristics of the soft pro mesh. The mentioning of pore size in square millimeter, it is not sufficient to compare the textile structures and the distribution of pores between two different structures sufficiently and in

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detail. However, I know we had the discussions low weight, lightweight, small pores, large pores; otherwise, this discussion in the surgical community would never have been possible to discuss about this. But it is too shortcoming to give an understanding of the consequences.

BY MR. BROWN:

Q. Doctor, all I want to know is this.

As of 2002, does the pore size under the LW mesh, does that characterize the Prolene® Soft Mesh as of 2002?

MR. ANDERSON: Objection, asked and answered.

THE WITNESS: This table cannot be used to say that soft pro mesh has some characteristics or some properties.

BY MR. BROWN:

Q. Doctor, is your answer then that that does not describe the pore size of Prolene® Soft Mesh as of 2002? Is that your answer?

A. My answer is this table describes the characteristics of this mesh that has been used in this study.

Q. And I understand that. Don't disagree with you.

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All I'm asking is, does the pore size as it describes it for LW, does that describe the Prolene® Soft Mesh pore size as of 2002?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: It would be easy for me to answer this if there is one answer, what is the pore size of a mesh, but there is not an answer like this possible. If, when I look to all these documents from the Ethicon people, where they struggled and fighted to find good values for getting the pore sizes, there has been a huge variation of data where they presented some estimates for pore size of the textile, of various textiles.

And so there is no one data regardless in what table that really truly is able to reflect the pore sizes of a textile. Every textile has some parts with very small pores and it has some other parts where it's different. So there is no one single value that can give this information, and, therefore, I cannot say that this is reflecting the characteristic of a specific textile.

BY MR. BROWN:

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Q. Doctor, I understand there's been a lot of changes over the last ten years with how people want to characterize things.

So is your answer that in 2002, the way you were characterizing pores in 2002, was the Prolene® Soft characterized as greater than 1 millimeter squared in 2002?

MR. ANDERSON: Objection, asked twice and answered.

THE WITNESS: Again, this table is not reflecting an experiment with soft Prolene® mesh; otherwise, it would have been stated there. Even in 2002, we prepared and made histograms distribution of the pore size of the meshes and presented these histogram of the various pores within a mesh. So even at 2002, we know that it has been a wide distribution of pore sizes within a textile structure.

However, we thought in many manuscripts that it is not a good idea always to discuss this specific topic in all of these manuscripts. That would expand the number of pages there. And that was the reason that we sometimes summarized it to some more simple terms.

BY MR. BROWN:

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Q. So, Doctor, let me just ask you this.

So as far as this article in Table 3 for pore size, you don't know if that has similar characteristics of Prolene® Soft Mesh? Is that fair to say, you don't know?

A. Again, there are a lot of --

Q. Either -- I've asked you a couple times, is the lightweight greater than 1 millimeter squared the pore size for Prolene® Soft.

Is your answer, I don't know, I can't tell you that?

MR. ANDERSON: Objection.

THE WITNESS: There are similarities to soft Prolene® mesh there with this mesh, but there is no indication that this is the soft Prolene® mesh.

BY MR. BROWN:

Q. And I know that. I'm just asking about the actual pore size.

And so as far as the pore size, are you saying that you don't know if the pore size of Prolene® Soft Mesh is greater than 1 millimeter squared? Is that what you're saying, as of 2002, you just don't know?

MR. ANDERSON: Objection.

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THE WITNESS: We knew at that time about the importance of pore sizes. We knew about the variation of pore sizes within a textile structure, but sometimes -- and in this table as well -- it was summarized to more simple data to give an impression to the reader or to help him in his interpretation of the results.

BY MR. BROWN:

Q. Doctor, let's talk about -- we ended yesterday with inflammation. Let's talk today about tissue integration. Okay?

A. That's okay.

Q. How would you describe good tissue integration into a pore?

A. If you want to reinforce tissues with the help of a textile structure, first of all, you have to apply surgical trauma to put the textile structure in there. Then this textile structure is placed in the wound. The following reaction during the following days is that you have the foreign body reaction, we talked yesterday, around the filaments.

And then in the pores, in the space between the filaments, there will happen some tissue reaction there. If you have a -- usually if you have a -- at best you have the regeneration of the

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local tissues there filling out the defect. That is the best healing you can imagine. And in the locations where usually meshes are placed, this is usually fat tissue. We know that muscles hardly ever showed some sign of regeneration, but fat tissue does show it. So if you have in the pores an ingrowth or regeneration of fat tissue laying there, this is an indicator of a widely unaltered wound healing in this patient.

The alternative would be that if you have excessive surgical trauma, if you have an infection there and/or if you have an excessive biomaterial associated inflammation there, then this regeneration will not happen, and then this time, the fibroblast will fill this defect, fibroblast with collagen, and then you have a scar there.

So scar indicates that you have a defect healing within the pores due to the local trauma that prevents this tissue regeneration with all the consequences of scar. We know that if there is some scar, it will always be a scar there. There is, to my knowledge, no way from the body to exchange scar by local tissue later on. So once a scar, ever a scar. And this scar will show some changes over time. It will demonstrate

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construction. It will show an impaired stretchability, as all scars. And impair -- or in relation to the extent of this scarring, you have maybe an increased shrinkage. You have an increase or you may have an integration of the local nerves in this tissue.

So on the one hand, you have the local tissue mainly indicated by fat tissue within the pores. That is I think a wound healing with the least functional restriction in this field. And on the other hand, you have a scarring process closing the defect. We know with all these textiles that there is no mesh which only shows pores, because at least at the linkage where the filaments are bound together, every knitted textile has some areas where you have this scarring process between the filaments.

Q. Now, Doctor, I've seen a couple of articles that you've written, and you talk about the fibrosis being limited to the parafilamentary region.

Does that indicate that there's good tissue integration?

MR. ANDERSON: Objection.

BY MR. BROWN:

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Q. Do you want me to restate that?

That if the fibrosis is limited to the parafilamentary region, does that mean that the granuloma is just around the actual fibers?

A. Of course it depends from the article and from the context there, but usually we wanted to describe exactly this -- that if the fibrosis is limited to the parafilamentary area and in the middle is fat tissue, then this is an indicator of better tissue integration.

Q. And when we talk about fibrosis, do we want fibrosis to be lower or higher?

MR. ANDERSON: Objection.

Go ahead.

BY MR. BROWN:

Q. Let me restate that.

Do you want the fibrosis lower or higher for good tissue integration?

A. There are several aspects if you are looking to fibrosis. Fibrosis is a need for fixation of the meshes. In this field, you may want a certain fibrosis if you attach it. Yeah.

On the other hand, there is no benefit. If the fibrosis fills out the complete pores, in contrast, what we have learned during all

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our work is that the filling out of the pores by scar tissue, this is related/associated with a lot of complications and complaints. And, therefore, it is -- I cannot imagine that there is any beneficial effect to construct or to induce scar tissue there.

Q. So if I'm hearing you right, some fibrosis is good for tissue integration; is that right?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: As we said yesterday, some inflammation, some fibrosis, the fibroblasts are essential cells for the body to overcome damages. These are for -- since million of year, or no, hundred thousand of years.

BY MR. BROWN:

Q. But you just don't want excessive fibrosis; is that correct?

A. If you define excessive as fibrosis that causes these bridging phenomenon which filled out these pores, if the fibrosis -- excessive fibrosis that hinders the physiological remodeling of the tissue, that is true.

Q. Would you describe excessive fibrosis as bridging fibrosis like you just spoke of?

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A. There are two levels you can describe excessive fibrosis. The one is the macroscopic, what you see in the OR when you do a revision operation --

MR. ANDERSON: Was that macroscopic?

THE WITNESS: Macroscopic, yeah.

So what we see in the OR when we saw -- when we made a revision operation at mesh and saw these clumsy, shrunken piece of something.

And the other is the microscopic, that you only be aware if you look with a microscope there. So at both levels, there is some name for what you don't want to have.

BY MR. BROWN:

Q. And whether you look at it macroscopically or microscopically, would you define excessive fibrosis as fibrotic bridging?

MR. ANDERSON: Objection, asked and answered.

Go ahead.

THE WITNESS: From the macroscopical view, I would prefer to name it more as encapsulation of the entire mesh. And that is what we got to weigh out, that we don't see the mesh any longer, we have this scar plate around. That is

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what we saw in the OR. And then we try to get an explanation and look with a microscope. And then we saw something that we later on called this bridging.

This is a phenomenon that can be seen only with a microscope, because you -- all these meshes where you macroscopically see this encapsulation, usually you see this bridging. But it can be otherwise round, that you don't see this macroscopic very thick scar plate there, but if you look with a microscope, you see that this scar bump or scar path in the pores that limits the function.

BY MR. BROWN:

Q. Let me show you Exhibit 9.

MR. ANDERSON: Can we take a break before we hit Exhibit 9?

MR. BROWN: I'm going to hit just a little bit of this bridging fibrosis and then we'll take a break.

MR. ANDERSON: So you're looking at Exhibit 9 and Exhibit -- is that 3?

MR. BROWN: Yes.

BY MR. BROWN:

Q. Doctor, that's your expert report. Doctor, the place I'm going to let you look at on Exhibit 9 is page 111, which has got the section

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"Fibrotic bridging."

And, Doctor, to make sure, on Exhibit 9, this is a paper you're the co-author of?

A. Yes, I'm a co-author.

Q. Doctor, if you would, if you would look at your expert report first on fibrotic bridging at the very bottom.

It should be the second to last sentence where it says, "This phenomenon."

Do you see that?

A. Yes, I see that.

Q. It says, "This phenomenon, known as 'fibrotic bridging' exists when granulomas, side by side, form a common outer fibrotic capsule joining each mesh fiber and forming a rigid 'scar plate' covering the whole mesh."

Is that your definition of fibrotic bridging?

MR. ANDERSON: Objection, asked and answered.

BY MR. BROWN:

Q. Doctor, I'll state it this way.

Do you agree with your expert report that that's what fibrotic bridging is?

MR. ANDERSON: Well, objection.

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THE WITNESS: I agree to this, yes.

BY MR. BROWN:

Q. And then if you look, Doctor, on Exhibit 9, page 11 under "Fibrotic bridging," the section.

A. Uh-huh.

Q. And, Doctor, if you look at the third sentence where it says, "Bridging occurs," do you see that? Third sentence?

MR. ANDERSON: Take your time. Read whatever you need to.

BY MR. BROWN:

Q. I'm looking upside down. Yes, "Bridging occurs."

Doctor, is it still your opinion today that "bridging occurs in all mesh modifications with a granuloma size around each mesh fiber exceeding more than half of the pore size of the mesh"? Is that still your opinion?

A. So if I look at this article, first of all, I see Figure 1. There is this distribution we just call about that we have been aware of the distribution of the pore sizes. On Figure 4, you see what I think is a good tissue integration with these pore size in there.

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MR. ANDERSON: Figure 4 on page 108 of Exhibit 9.

BY MR. BROWN:

Q. Doctor, since you brought that up, I'll ask that question.

MR. ANDERSON: Can he finish his answer?

MR. BROWN: I just want to make sure he answers mine and then I'm going to --

MR. ANDERSON: Maybe he's trying. We don't know.

BY MR. BROWN:

Q. Doctor, my question is this --

MR. ANDERSON: Objection.

BY MR. BROWN:

Q. Where it says, "Bridging occurs in all mesh modifications with a granuloma size around each mesh fiber exceeding more than half of the pore size of the mesh," is that your opinion today with regard to what bridging fibrosis is?

A. This sentence says that if you have this, these very huge granuloma sizes, then you always have the bridging.

Q. So in fact --

A. You may have bridging or you will

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have bridging even if the granuloma size is less. This sentence has been one of the first attempts to get an idea to predict bridging.

Q. Okay.

A. In this experiment that is described by reference 47, there it was the first time that we had the impression that it can be related to the size of the granuloma, but this is not sufficient.

Q. So bridging fibrosis, those were the granulomas from one fiber to another fiber, the granulomas are actually touching each other; is that right?

A. No, that is not right. It is not the granuloma that necessarily bridges between the filaments, but it is the appearance of this scar throughout the pores formed by fibroblasts and collagen. And the absence of this bridging, you see in Figure 4F that you don't see this bridging.

Q. So 4F, there is not bridging fibrosis; is that correct?

A. 4F in this image, there is no, that is correct.

Q. And so, Doctor, I just want to come back to your expert report to make sure I understand correctly.

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When the granulomas touch and are side by side, as you say, that's when you have this scar plate that forms over the top of the pores; is that right?

MR. ANDERSON: Objection.

Do you understand his question?

THE WITNESS: Yeah, yeah.

MR. ANDERSON: Okay. Take your time.

THE WITNESS: If you had this bridging, this scar, this scar, and you're coming to the foreign body, this scar usually goes into the fibrotic capsule there, because the primary granuloma is surrounded by scar tissue, and then if it's close together, then this scar crosses the entire pore. It is not necessarily the inflammatory infiltrate that has to have a contact between the filaments there. So that is sometimes the confusion that may appear that you sometimes refer to the infiltrate there and sometimes to the scar formation there.

BY MR. BROWN:

Q. Doctor, if you look on your Exhibit 9 --

A. Uh-huh.

Q. -- do you see, Doctor -- let me ask

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it this way first.

On your expert report, you say, Doctor, that the granulomas -- strike that.

You say "'fibrotic bridging' exists when" the "granulomas, side by side, form a common outer fibrotic capsule."

So are you saying that the granulomas need to be side by side, touching, so that a scar plate then forms over the top?

MR. ANDERSON: Objection, asked and answered.

Go ahead.

THE WITNESS: This expresses that you have the outer fibrotic capsule around the fibrotic capsule, and then you have this joining band in between. It is not necessarily that when you measure the size of the foreign body granuloma, that this has to have direct contact. If you are looking to the images there, you see that the foreign body granuloma can be -- can have a little -- some sort of distance, but, nevertheless, you have a filling out of the pores by scar formation.

BY MR. BROWN:

Q. Doctor, then --

A. So if you like -- if you have some

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pictures and images, we can have a look to it, and then we have to define on the images, that is a foreign body granuloma, that is scar tissue, that is the inflammatory infiltrate, that is a fibrotic capsule. And then the only important question then is, did you see fat tissue within the pores or did you see scar tissue. I think that is the most relevant question.

Q. How much space do you need between the granulomas for the fat tissue to grow in between?

A. This is not -- sorry.

This is not the right question, because it depends from the time point. If you are measuring the foreign body granuloma, the size of the foreign body granuloma at various time points, after 21 days, you have a larger size of this granuloma. After 90 days, you have a smaller size of the granuloma. So the size of the granuloma changes over time.

Nevertheless, if you are looking after two years whether there was some bridging in this field, you have some textiles where you have this bridging and you don't have -- or you have some where you don't have it. And, therefore, at all the

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human explants, we measure the distance between the filaments. And we have seen from our experience from all our analyses that if you are looking at the distance between the filaments, you have a critical distance of about 1 millimeter if you have a polypropylene filament there. And for the PVDF we found that less, was about 600 microns or 500 microns in this field.

When you have a smaller distance, you usually have bridging in this. When you have larger, you usually don't, there is less risk for getting this bridging there. So it is the distance between the filaments, because the distance between the granulomas is very hard to objectify and to measure precisely, it depends from many things.

Q. Doctor, don't we measure the size of granulomas all the time? I mean, you -- let me restate that.

You've measured in your studies the distance of the granulomas. Correct?

A. We measure the distance -- for defining the distance for bridging, we measure the distance between the filaments. And that is what is done in -- at the analysis of the human explants as well.

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Q. But, Doctor, don't you also measure how much granuloma forms around the fibers?

A. Yes, of course. And, therefore, we once had the idea that the size of the granuloma predicts the later onset of a bridging. In an animal experiment comparing different materials, in this setting, we had the impression that the effect of bridging was related to the size of the granuloma. But there were a lot of other confounders.

Q. And --

MR. ANDERSON: Wait. Let him finish. Go ahead.

Do you have more to say?

THE WITNESS: No.

MR. ANDERSON: Okay.

BY MR. BROWN:

Q. Doctor, is it generally understood or published anywhere on how much distance between the granulomas -- strike that.

Is it generally recognized in any studies on how much space is necessary between the granulomas for fat tissue to grow in between?

MR. ANDERSON: Objection. Go ahead.

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THE WITNESS: So the first statement was whether it's generalized accepted or --

BY MR. BROWN:

Q. Are there any studies that you're aware of that identify how much space is needed between the granulomas for fat tissue to grow in between?

A. So, first of all, the general statement that there is bridging when the filaments are coming close together, I think it's generally accepted, it is in the documents from Ethicon, it is in the documents of the literature. So I think there is no criticism to this conception.

Unfortunately, experimental measurements or measurements at human explants to define what is the critical border for bridging, there are only few data. And, unfortunately, I think the study which clearly showed this was done by ourselves, where we looked at the point where we saw some bridging, it is this study that first author is Joachim Conze.

Q. Doctor, did that study say how much space was needed between the granulomas for tissue to grow in between?

A. This study, amongst others, says a

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lot of things. It says at what limit, at what distance we have a high risk for bridging scar tissue, not tissue ingrowth. It was not a study to check tissue ingrowth in general. It was just referring to the problem of scar bridging or whatever unit. There are a lot of possible ways to misunderstand this, but...

Q. Doctor, this is all I'm asking, is if you know if there is a distance between the granulomas that allows the tissue to integrate.

Do you know that distance?

MR. ANDERSON: Objection, asked and answered. He said it depends on time point.

MR. BROWN: He hasn't answered it.

MR. ANDERSON: Yeah, he said it. He said it depends on time point. You heard that.

BY MR. BROWN:

Q. What I want to know is, can you tell me if it's 10 microns, 20 microns, 100 microns, what is the distance between the granulomas for tissue to ingrow?

MR. ANDERSON: Objection.

BY MR. BROWN:

Q. And if it's a difference between days, then you can tell me the difference in days if

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you know that.
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: If you want to know what is the distance for tissue ingrowth, I think it is 50 microns maybe. A cell has 5 microns. And if you define tissue as three or five cells together, then you are in the range of maybe 50 microns, then you have some sort of cell ingrowth.
If you are discussing the problem of bridging, scar bridging, it is our current knowledge, and was for a long time, that it is about 1 millimeter for -- if you use Prolene®. And this is in agree -- in accordance with what Klosterhalfen said at all these meetings, what has been on the PowerPoint presentations when they define the requirements. So to avoid this scar bridging, 1 millimeter is considered as critical.
BY MR. BROWN:
Q. Let me ask you one or two more questions and then we'll take a break and we'll talk about the 1 millimeter.
Doctor, let's come back and look at Exhibit 9. Under "Fibrotic bridging," it was that sentence that you and I were talking about, which

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is, "The bridging occurs," the third sentence?
MR. ANDERSON: He's going back to this sentence.
MR. BROWN: Yes.
BY MR. BROWN:
Q. Doctor, why would you say in that statement that, "Granuloma size around each mesh fiber exceeding more than half of the pore size of the mesh causes bridging" if -- well, let me just ask this.
Is that sentence not stating that if the granulomas -- strike that.
On your third sentence there when it says, "Bridging occurs in all mesh modifications with a granuloma size at around each mesh fiber exceeding more than half of the pore size of the mesh," isn't that saying that bridging occurs when the mesh or when the granulomas touch each other?
A. This sentence, as I told you before, is -- the reference is 47, it's in animal experiments. We can go to this study if you like and discuss these studies, but in fact, it has been -- as I tried to explain before, it has been the first assumption from this animal experiment to predict this phenomenon, but just on the basis of

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this animal experiment comparing different things. So it is not sufficient to predict the risk for bridging by only looking to the size of the granuloma.
MR. BROWN: Let's take a break.
- - -
(A recess was taken from 10:32 a.m. to 10:45 a.m.)
- - -
BY MR. BROWN:
Q. Doctor, let me get you to go back and look at Exhibit 15, if you would.
A. 15?
Q. Right here.
Doctor, if you'll take a look at page 132, if you look at page 132, Doctor, I'm looking on the right column here.
And if you look where it says, "The size of the granuloma margins"?
MR. ANDERSON: Top part or bottom part?
MR. BROWN: Top part.
MR. ANDERSON: Got it now.
BY MR. BROWN:
Q. It's about right in the middle where

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it's got some different measurements.
A. Yes, I see it.
Q. Now, I'm looking at the -- let's just look at the 90 days for the lightweight mesh.
It's got a granuloma size of 43.5 microns; is that right?
A. That is right. So written in the text.
Q. Now, Doctor, if you would, take Exhibit 13, which is -- you can hold them both open.
MR. ANDERSON: 13 is that PowerPoint?
MR. BROWN: Yes.
BY MR. BROWN:
Q. Looking on the fourth page of Exhibit 13, which is the picture of the pore, do you see that, Doctor?
A. Yes, I see this.
Q. Now, Doctor, here's what I want you to explain for me, is explain --
Doctor, you can use the very --
Do you see where that yellow line is that's going north and south?
A. Yes, I see this.
Q. Do you see, about 90 percent of the way up, right where that pore or that filament is

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going in about a 30-degree angle?
A. Yes, I see this.
Q. Now, Doctor, help me explain, or help explain to me, how, with a granuloma of around, what did we say, 43.5 microns, that that can bridge with another fiber that's almost 1,200 microns apart?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: As I tried to explain before the break, bridging cannot reduce to the size of the granuloma. And, of course, if you sign in this figure the granuloma was 43 microns there after 90 days, you have a smooth layer around the filaments. If you marked it after 7 days, you have a bigger size of the granuloma. After 21 days, you have another size of the granuloma coming around these filaments here in this field. But, of course, it is not filling out -- the granuloma is not filling out the entire pores. That is -- I think this is a simple fact, if you are coming from a size of 40 microns and have a construction like this one. So, therefore, I just want to repeat that the filling out of the pores by scar tissue is not decisively defined by the size of the granuloma.
BY MR. BROWN:

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Q. And, Doctor, you mentioned that the pores -- I'm sorry, strike that.
You mentioned that the microns can change with the different days.
And I think from the literature, the greatest degree of granuloma was 59 microns at 21 days; is that right?
A. The greatest size of the granuloma in this chapter is 150 microns.
Q. For the lightweight mesh, Doctor?
A. For another mesh. So it varies depending on the structure of the mesh. But the biggest in this setting, only in this setting, the biggest size of the granuloma is 150.
Q. What's the biggest size for the lightweight mesh, Doctor?
A. For the lightweight, in this experiment, it is -- so it is 59 after 21 days.
Q. Okay.
And, Doctor, you would agree with me that just by measuring the granulomas, that those granulomas would not touch in this pore that I've shown you in Exhibit 13; is that correct?
MR. ANDERSON: Objection.
Go ahead.

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THE WITNESS: In the middle of these, with the distance, if you have a granuloma size of about 60 microns, around 60 microns, and you have to consider it on both side of the filaments, means 120 microns, then at every distance that is bigger than 120 microns, you will not see this contact between these two granulomas. However, this does not reflect reality, because you usually not always have circular granuloma, but it has some different shape.
BY MR. BROWN:
Q. Now, Doctor, you've talked about the 1 millimeter pore size as being the distance that you want a pore to be; is that correct?
1 millimeter between the fibers; is that right?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: We have observed from our microscopically evaluations that when we have a cross-section where the distance between polypropylene filaments is 1 millimeter, then we have good chance not to see this scar bridging. Therefore, we are convinced that 1 millimeter distance is a critical border. However, we know that sometimes cross-section is showing a filament

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that is more or less diagonal. So if you -- may I draw? Yeah?
BY MR. BROWN:
Q. Sure.
A. So sometimes you have a cross-section with a filament like this, but it may be that this is a bending, a binding here where the filaments are linked together. And if you make a cross-section here in this field, then you have a distance of 1 millimeter, but maybe there is not a distance to the other. Therefore, we know that there -- that you need these 1 millimeter to all sides.
Q. All right. Now, Doctor, is the 1 millimeter distance that you are talking about, does it take into consideration the radius of the fiber?
A. This general border of this 1 millimeter does not -- or we didn't modify this 1 millimeter border for various sizes of the filaments, though we know that, maybe for the old or that for the very thick-sized filaments, maybe the distance has to be bigger. But most of the meshes that are currently available have a size of the thread between 90 and 120 microns. And in this range, we didn't see this big difference.

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Q. And, Doctor, did you take into consideration whether the fiber was multifilament or multifilament?
MR. ANDERSON: Did you say multi or multi? You mean mono or multi?
MR. BROWN: Did I? I'm sorry. Thanks.
BY MR. BROWN:
Q. Did you take into consideration for your 1 millimeter distance whether the fiber was multifilament or monofilament?
A. The experimental basis for the definition of this critical limit was done with monofilaments, and there is only limited experience with multifilaments, as well in the collection of human explants from Professor Klosterhalfen, because multifilaments are not very often used in Germany.
Q. Now, Doctor, this 1 millimeter theory that you have, has it been generally accepted by any societies?
MR. ANDERSON: Objection.
THE WITNESS: We are presenting this, the advantage of, let me say, large pores of the tissue ingrowth for the benefit of the patient since late '90s. And so far, I realize there has no --

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I've -- I didn't -- never notice any scientific criticism to the fact that you have this scar formation that pore size is critical for tissue ingrowth, but I know a lot of studies from others that confirmed this, the importance of the pore size. Yeah.
BY MR. BROWN:
Q. Doctor, what other studies can you point to that are outside of your group here in Germany who have stated that you need 1 millimeter between the fibers or bridging fibrosis takes place?
A. As I said, the studies or the data for defining where exactly this critical border is, this is limited. This is limited to the studies of our group.
But on the other hand, the proof that smaller, real small pores, there is a study of Weyhe, who clearly showed that fleece-like structures with very, very small pores, that they have a huge intensified inflammation despite reduction of the weight. So this is -- Weyhe has made one of the studies that confirmed the impact of pore size for the inflammation. And Bellon is -- the group around Bellon, they confirmed this by experimental studies as well.

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Q. Weyhe is the --
A. W-E-A --
MR. ANDERSON: W-E-Y-H-E.
BY MR. BROWN:
Q. Do you know what year that study was in, Weyhe?
A. In the Journal of Surgery, maybe 2006.
MR. ANDERSON: '7, I think.
THE WITNESS: Around.
BY MR. BROWN:
Q. And then is there Bellon, is that --
A. Bellon.
MR. ANDERSON: B-E-L-L-O-N.
BY MR. BROWN:
Q. And what year was that study?
A. They published I think more than 25, 30 articles, making a lot of experimental work since the '90s. So permanently every year one or two articles, one studies, and some of them are focused on PTFE, but some are having it in the title that they showed lightweight, large pore is better than the other.
Q. Does Bellon, their group, do they say that you need 1 millimeter pore sizes or bridging

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fibrosis take place?
A. No. They -- so far I know and remember the articles, they were not able to give a specific data to define this.
Q. I want to talk about effective porosity, something you've written about in your report; is that correct?
A. Yes.
Q. Doctor, when you want to determine how a mesh will react in the body, you want to simulate the environment it's going to be placed; is that right?
A. Please say that again?
Q. Yes, yes, yes.
When you want to determine how a mesh is going to react in the body, you want to simulate that place it's going to be located; is that right?
A. I don't know what is meant with simulate the situation, in what regard this is meant.
Q. Sure.
When you want to determine how a mesh is going to react in the body, you want to make it similar to what's going to happen in the body with regard to forces; is that correct?

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MR. ANDERSON: Objection.
You can answer.
THE WITNESS: The aim is not just to make it similar. As Professor Williams pointed out in his report, or some others, there is no one single setting to make it similar to the human situation. But you have to collect lots of data from different settings, from different models and put them all together and find the best solution to compensate your requirements that you have defined there. That is the way you may find the optimum. But it is not that you are looking for a model that can completely mirror the situation in the humans.
BY MR. BROWN:
Q. You want to try to get it as close as you can, though; is that right? With all the data taken together, you want to get -- strike that.
The testing that you do, you want that testing to be as close as it can be to what's going to happen in the body so that you know how that mesh is going to react in the body; is that right?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: There are many

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different tests to see what happens in the body. There are many different models to see. And there is no one single test that can reflect what happens in the body. The challenge was, if you refer to this effective porosity, the challenge was that -- we have been asked to demonstrate typical -- specific characterization of mesh materials which are able to predict the tissue ingrowth, the risk of some shrinkage or other complications.
And I started in 2010 to ask all the manufacturers in Germany to provide some textile data to make this characterization of this mesh material. And they sent in a huge amount of different values there, different technology to assess porosity, stability, elasticity, a mixup of various methods.
So, finally, I got a huge Excel sheet there with all these data from the different products of the different manufacturers, but all these properties or variables are not sufficient to define critical differences between these things. And that was the reason that we have to think about it, to simplify it for the surgeon and to give a risk indicator for what they may expect, what is the risk for them, what they may expect, what happens

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after using this mesh materials. And then we came up with a solution that it is porosity, because this is the only one that is widely -- yeah, that predicts a little the tissue integration, and this can be standardized in an objective fashion to compare different textile structures.
BY MR. BROWN:
Q. Doctor, when you determine effective porosity, you're saying that there's going to be -- there needs to be 1 millimeter of distance between the fibers. You put a strain on the mesh, and if that strain brings the fibers below 1 millimeter, then it's not effective; is that correct?
MR. ANDERSON: Objection.
THE WITNESS: The principle behind this conception of an effective porosity is, first of all, that you need a certain pore size to lower the risk for this bridging.
BY MR. BROWN:
Q. And that's 1 millimeter. Correct?
A. No. That is in principle, that is the basic idea in between or behind this conception. So the next point was to get a measurement that can reflect the area where these large pores are put in or are measured. And this area of the good pores is

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named as effective porosity in relation to the total size of this.
So this was the principle, and we established this method to do so. Then if we refer to the literature, and there -- as I said, there is only this reference from Conze, that we took as the critical value for the use or when polypropylene is used, this 1 millimeter to make the cutoff for the good pores and the bad pores.
Q. And then you talked about a strain that's being placed on the mesh, and if that strain causes it to be less than 1 millimeter, then the pore is not effective; is that right?
A. So this was --
MR. ANDERSON: Objection.
THE WITNESS: First of all, this was the conception of the effective porosity, to define a large pore in all sides with a certain diameter. This was, from our point of view, satisfying in a field of tension-free repair. We know that with pores that are bigger than this, we have a lowered risk of fibrotic bridging in this.
In the case of where a tension free cannot be accepted totally, as in the hiatal area, in my field, or in the pelvic floor as well, then

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you have to consider this collapse of the pores. And if you have a -- then, of course, this can be reflected by mentioning the effective porosity.

And we were surprised that there are a lot of textile structures which show, even at very low strain, a completely collapse of the pore sizes. And from our experience, this is a -- has been a very good explanation for what we saw in -- with the tissues of the explanted meshes. When you look to the -- with the microscope to these explants and look to the scarring there in this, then this change under strain that has not been considered before, to my knowledge, in the literature, this is a very good reflection of what happens in the tissues.

BY MR. BROWN:

Q. Doctor, the strain that you applied in your article, "New Objective Measurements to Characterize the Porosity of Textile Implants" in 2007, did that strain come from measurements for hernia repair?

- - -

(Deposition Exhibit No. Klinge-16, Article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants", was marked for

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identification.)

- - -

MR. RESTAINO: Did you mark that as a new exhibit?

MR. BROWN: As 16, Exhibit 16.

BY MR. BROWN:

Q. Doctor, the strain that was placed, was it derived from hernia strain or from pelvic floor strain?

MR. ANDERSON: Give him an opportunity to look at the document, if you would.

MR. BROWN: Ben, if we're going to read each and every document, this is one that's cited in his expert report, it's a real waste of time.

MR. ANDERSON: I didn't ask him to read the entire document, but he has a right to be able to put your question into context. So just to throw out a question and hand him a document is not fair. He's written a lot of articles.

And, for the record, he has not taken the time to review each and every word of any of the exhibits you have given him, but he has glanced at them in order to refresh his memory to be able to answer your questions.

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MR. BROWN: Ben, it's cited in his expert report. He talks all about it.

MR. ANDERSON: He cites 200 things in his expert report. You expect him to remember everything in there? Come on.

- - -

(Deposition Exhibit No. Klinge-17, Expert report of Prof. Dr. Thomas Muhl, was marked for identification.)

- - -

BY MR. BROWN:

Q. Doctor, you agree there was a strain that was put on the mesh; is that right?

A. The strain was 10 kilogram at a width of the sample of 10 centimeters, so, finally, it was a strain of 9.8 newton per centimeter there that was put in this setting to the mesh.

Q. And is that force derived from hernia pressures or from pelvic floor pressures?

A. This force reflects our knowledge that we should be below 16 newton per centimeters.

MR. ANDERSON: 16 as in 1-6?

THE WITNESS: 16 newton per centimeters. For the range, we assume to be quite physiological strain in either area of the abdominal

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cavity. It was not specific for abdominal wall, not specific for the groin or pelvic floor or hiatal area. It was -- for the demonstration, what happens, first attempts to test this with a strain where we felt that it is not beyond any reasonable ranges.

BY MR. BROWN:

Q. Doctor, if you look on the abstract on the very first page, the last sentence, it says, "Further in vivo studies have to investigate, whether the preservation of a high effective porosity under stress may help to improve biocompatibility of textile implants."

Doctor, do you know if this effective porosity idea that you have, do you know if that was ever tested in vivo?

A. I think it is there is no -- I don't know any specific -- in vivo, if you are thinking of an animal experiments, we tested it ourself in the hiatal area. We compared it to, or we used two different devices, one with a structural instability and one with a high structural stability. And we saw an intense fibrosis with a structural instability. That is a confirmation in vivo, in an animal test. There are on the market --

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Q. What was the name of that study?
A. What?
Q. What was the name of that study?
A. It is a study that has been done in the project where we developed these visible meshes with the FEG here.
Q. What date was it published, do you know?
A. It is ongoing, there is in preparation.
Q. So it has not been published?
A. Not been published yet.
Q. Is this documents that you have on your computer about these studies?
A. I have documents, yes.
Q. Doctor, there -- go ahead.
A. But there is -- in vivo, there is -- you may not call it a test. But if you are looking to all the different devices that are used in humans, you have differences in the structural stability in the moment. So we will learn in the near future whether there are some of these devices behaved better than others.
Q. Doctor, I'm showing you, this is Dr. Muhl's report. And it's marked as Exhibit 17.

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Doctor, if you look on page 8 of Dr. Muhl's report.
MR. ANDERSON: Did you say 17? 17?
MR. BROWN: Yes.
MR. ANDERSON: What page did you want him to go to?
MR. BROWN: Page 8. Page 8 of his actual report, Doctor.
MR. ANDERSON: This one?
MR. BROWN: Yes.
BY MR. BROWN:
Q. Doctor, you have relied on Dr. Muhl's testing to come up with effective porosity; is that correct?
MR. ANDERSON: Objection.
THE WITNESS: I refer to these measurements, yes.
BY MR. BROWN:
Q. And, Doctor, if you look, Dr. Muhl did not actually test the Prolift®. He tested Prolene® Soft Mesh; is that correct?
MR. ANDERSON: Objection.
THE WITNESS: So far -- we can have a look there.
BY MR. BROWN:

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Q. Doctor, let me --
A. Somewhere he clearly described what he's using and the reason why he's using it.
Q. Doctor, let me ask you this.
On page 14, that's not the body of Prolift®, is it?
A. Again, we have to look. I know there is somewhere he described why he took the body of -- or the arms of the Prolift® and why he took the body of soft Prolene® mesh or Gynemesh® and the reason for this and where he explained what is depicted there. So we can -- yeah. I will find out for you and can explain, but I know it's written there somewhere. So I don't see -- I'm not able to explain it just by looking through this.
Q. Doctor, all I'm asking, on page 14, that piece of mesh, that's not the body of Prolift®, is it?
MR. ANDERSON: Well, objection, asked and answered. He clearly just answered your question and said he would have to look. If you want him to look, he will look.
MR. BROWN: Ben --
MR. ANDERSON: What?
BY MR. BROWN:

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Q. Let me ask you this, Doctor.
That piece of mesh on page 14, is that in the shape of Prolift®?
A. No. The shape of Prolift® is different to the shape of this.
Q. Thank you.
Dr. Muhl is not a medical doctor; is that right?
A. He's not a medical doctor so far I know.
Q. And Dr. Muhl was holding the piece of mesh and then pulling it in one direction.
Is that your understanding?
MR. ANDERSON: Objection.
THE WITNESS: No. He did it in two directions.
BY MR. BROWN:
Q. So he pulled it in two directions?
A. And he made an uniaxial strain to this, and then he repeated this measurement in a perpendicular direction.
Q. And uniaxial means that you're pulling from -- what does uniaxial mean to you -- scratch it. Let me just make it one.
What does uniaxial mean to you?

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A. Uniaxial means that you have one main direction where you applied the force, with all the limitations, that it depends that is affected by the direction of the machine fibers, that it depends from the width of the sample, that it depends from the length of the sample, it depends from the load, from the terminal load, because usually it's a nonlinear reaction, so all these limitations are there.

Q. Now, Doctor, the forces in the pelvic floor are not coming from one direction. Correct?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: The forces in the pelvic floor, there are many different areas to be considered. There are many different directions to be considered. There are different models to be considered. And so far, what I know from all the discussions with our pelvic floor colleagues, there is an ongoing --

BY MR. BROWN:

Q. Doctor, I'm just asking you if the pelvic floor forces come from one direction. That's all my question is.

So does the pelvic floor forces come

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from one direction?

MR. ANDERSON: Same objection. And he was trying to answer your question, so please go ahead.

BY MR. BROWN:

Q. If you just answer my question.

MR. ANDERSON: Well, he's trying to.

THE WITNESS: I want to come close to your question, of course. There is an ongoing discussion how to consider the biomechanics of the pelvic floor best, either by considering flat areas that later on may be reinforced by meshes, or whether it can be reflected best by assuming that you have some ligaments keeping the -- or stabilizing the pelvic floor. And reflecting this ongoing discussion there, there are -- there should be considered different models how this mechanical strain has to be considered for the pelvic floor. For those guys, believing that it's mainly ligaments. And if you make a reinforcement of the tissue, mainly to reinforce the ligaments, the assumption that you have an uniaxial strain in this field may be the best we have in the moment; whereas, in other areas where you believe that it is an area that has to be reinforced, a multiaxial

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strain in all directions may be even better appropriate to simulate this, to reflect this. However, we are very limited to get a biomechanical characterization in multiple directions.

BY MR. BROWN:

Q. And in the pelvic floor, there are multiaxial pressures. Correct?

MR. ANDERSON: Objection.

THE WITNESS: In the pelvic floor, there are structures that are stressed from multiple directions.

BY MR. BROWN:

Q. And if you have forces from multiple directions, that can affect the mesh different from forces in one direction. Correct?

A. From my understanding, that is correct, that it is -- that the uniaxial has its limitations.

Q. Now, Doctor, the force placed on the mesh arms, if you go back to page 12, ranges from 0 grams to 1,000 grams; is that correct?

A. That is correct.

Q. Doctor, where did you come up with the theory that there is 500 grams or 1,000 grams of pressure for the arms of Prolift® in the pelvic

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floor?

MR. ANDERSON: Objection as to the characterization.

Go ahead.

THE WITNESS: The idea was to test whether the textile structure collapses under some mechanical strain. And, therefore, we have to define the range. We have to test this one. Of course, if you imagine any biological system, you have various different levels of mechanical strain. You have peak strain, you have a permanent strain and so on. And so there is not one figure that reflects the biology completely.

But if, considering the literature, for example, we -- I have the -- or I'm sure that the strain is less than 10 newton per centimeter, and, therefore, we made this investigation to see whether in this -- under this mechanical strain, you see -- already see a collapse of structure and to what extent you see this deformation of the mesh.

BY MR. BROWN:

Q. Doctor, did you --

A. And, therefore, we choose this range for up to 1,000 grams, because we were convinced that it is not helpful to see it with a higher

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mechanical load.
Q. Doctor, did you decide that the mesh should be tested between 0 grams and 1,000 grams or did Dr. Muhl decide that or did you both?
A. Both.
Q. And, Doctor, again, what specific literature or what specific experience do you have that tells you that there is up to 500 grams or 1,000 grams of force on the arms in Prolift®?
MR. ANDERSON: Objection, asked and answered.
Go ahead.
THE WITNESS: There are a lot of -- so I had -- I looked to all these -- to many articles, looking to the biomechanics of the pelvic floor. And I realized that, again, the tissue usually ruptures at forces that are more than 10 newton per centimeters, or 20, 20 newton per centimeters. So, therefore, we were quite sure that in the pelvic or the pelvic tissue, there is a limit of 20 newton per centimeters as an upper force.
And we didn't want to test in a supraphysiological range there, and, therefore, we decided to be below 1 kilogram. The decision to take 250 and 500 depends on the equipment and on the

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setting. It can be other figures as well. And I was very satisfied that, when I looked through the Ethicon documents, they made their testing in a similar range as we did. So I feel very comfortable to have this testing in this mechanical load.
BY MR. BROWN:
Q. Doctor, these loads that are applied, you're not able to identify these are appropriate loads based upon your experience and knowledge with the pelvic floor, your personal knowledge with pelvic floor; is that right? It's based on literature; is that correct?
A. It is based on literature, it is based on our experience of tissues, of the mechanical resistance to strain of tissues there. It is not based on my personal stretching of vaginal tissues.
Q. You say a couple times that you've relied on some literature.
Can you tell me what that literature is that you relied on that says that there's 500 grams to 1,000 grams of force on the Prolift® arm in the pelvic floor?
MR. ANDERSON: Objection.
Go ahead.

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THE WITNESS: There is no -- to my knowledge, there is no detailed literature confirming that 500 grams is the best value ever, but if you're looking to the biomechanical analyzers from the French, mainly Cosson, his group, there is a lot of studies indicating that you have to consider a load of less than 10 newton per centimeter.
BY MR. BROWN:
Q. So Cosson says you have to consider less than 10 newtons per centimeter?
A. 85, they tried to define this comfort zone, yes. In this group, they provided a lot of these data.
Q. And how less than the 10 per centimeters?
A. What?
Q. You said that Cosson considered less than 10 centimeters --
A. Newton. Newton.
Q. Sorry. Newtons per centimeter.
So what did Cosson say was the pressure on the arms in Prolift®?
A. I didn't make any statement to this, but we can look through all the literature of this

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group to look whether he has said it. So far I remember, they made some general measurements in tissues in pelvic floor trying to find a or to get a biomechanics estimate of the burden there. However, I know that it's very difficult, and the people from Ethicon, they know it as well, that there is no precise model which really can give exactly the data for this. Therefore, it is impossible, if you ask me that I present them, it is not possible, as everyone knows. But you can try to find some estimates to come in this field.
Q. Doctor, when you place a piece of mesh in the pelvic floor, it's going to very quickly begin to form granulomas that you've talked around, around the fibers.
Would that affect the strength of the mesh and how different it might look -- let me strike that and let me restate that question.
Doctor, when you place a piece of mesh in the pelvic floor, it's going to begin to have tissue around it.
Does that give it more strength which would resist some of this stretching as you've indicated in page 12 of Dr. Muhl's report?
A. I totally agree that if you have a

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tissue ingrowth, let's say a incorporation into dense scar formation of a mesh, then if you would repeat this measurement with all the scar formation around, you may not see this collapsing structure, because everything is completely stiff.

So -- but if you do the measurement, the mechanical strain, without this full tissue integration, and this may occur within the first time, in the first hours, within the first days, where you still have the option for the pore size to show this deformation, then you have to consider and you have to know that you have this collapsing of these structures. And I've seen some videos where the Prolift® has been implanted, and you see in the videos that the arms showed this deformation and curling as you see it in this testing.

So at least in this moment, and at least for the arms, I think it should -- it has to be considered as a serious change. And I'm deeply convinced that the Prolift® that you take out from the package, it -- you have a certain appearance of the arms. And this is different to what is placed in the body.

Q. Doctor, let me just ask you about that video you just mentioned.

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That video is a video of the Prolift® being implanted into a patient, and the arms you're seeing are when they're pulling them out through the cannula; is that right?

A. Yes. Out of the body and -- yeah.

Q. You're not talking about a video looking at the mesh in the body two weeks later. Right?

A. I have some -- or if you look to explants, and Professor Klosterhalfen did it extensively, then in many of these explants, he saw this curling, this folding of these materials.

So as we see it very, very often, we don't think that it is only done intentionally or not intentionally by the surgeon, but, again, this finding of the histological sections where you see this curling that he described there, that was I think a good explanation can be seen in this mechanical testing. And, therefore, we believe that this mechanical testing of a textile structure's effective porosity under strain is helpful to predict the risk for these scarring, tissue integration.

Q. Doctor, let me just ask my question again, which is, the video you saw was not a piece

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of mesh in the body two weeks after implantation, seeing how it's actually working in the body; is that correct?

A. No. That is -- yeah. Okay. Yeah. That is right.

Q. Okay. And then --

A. Is there any video?

MR. ANDERSON: Unless he's holding out.

BY MR. BROWN:

Q. When you said that Dr. Klosterhalfen in his explants has shown some of this pore deformation that you talked about from this testing that Dr. Muhl did, is that on the Prolift®? Is that what you're talking about?

A. As I -- yeah. He has seen it for the Prolift®, and I think he has, yeah, made an analysis in particularly for the Prolift® and made an analysis of Prolift® explants where we saw this. And, in part, he reported in some of the documents about his experience on Prolift® explants.

Q. And have you seen this kind of reaction that we see in page 12 with the Prolift®?

MR. ANDERSON: This is 12.

Have you --

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THE WITNESS: This one.

I personally don't have an explant of a Prolift®.

BY MR. BROWN:

Q. Okay. And have you seen, whether it be explants, pictures, from Dr. Klosterhalfen where you see results like page 12, any of the results on page 12?

MR. ANDERSON: Asked and answered, but go ahead.

THE WITNESS: I didn't see his results in -- for -- of his evaluation of the Prolift® meshes. If I remember correctly, it was done in evaluation for Ethicon Norderstedt.

BY MR. BROWN:

Q. Now, Doctor, is there anything that you can point to that says that there is going to be a constant strain of 1,000 grams on the Prolift® when it's in the pelvic floor?

A. A constant strain of 1,000 grams to a textile structure, I hardly can imagine that there is -- that it is -- if you believe constant for two weeks, for example, constant strain of two weeks on a textile to -- that is -- from my knowledge, that is in principle impossible.

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Q. Doctor, is that the same for 500 grams of constant strain?
A. Constant strain, 500 grams, two weeks, no, I don't think so, but -- yeah. I don't think so.
Q. What about a week, Doctor?
A. I don't know.
Q. And, Doctor, when Dr. Muhl was testing this mesh, he was holding it still on one side and then pulling it; is that correct?
A. Yes.
Q. And, Doctor, if there is 1,000 grams of force being placed on a mesh, is the other side being held right in place, or is the body a little more elastic and it's going to move with it?
MR. ANDERSON: Objection.
Go ahead.
BY MR. BROWN:
Q. Do you want me to restate the question, Doctor?
Let me ask it this way.
Are you aware of the body holding one side of the mesh perfectly still while the other side is stretching it with 1,000 grams of force?
A. I'd have to think about, just from

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the physics, what this -- this is a problem of the whole system, whether it changes or not. If you measure a force between two points of 1,000 grams, it is independent of whether the entire system is switching or is moving. So, therefore, the -- what happens to the entire system has not an impact on this force. What you may indicate on is that if the other part is moving as well, then you have a rapid loss of the force there. That in fact is true. But to -- if you want to measure what happens to a textile structures at a certain strain, this is not affected what happens otherwise around.
Q. So, Doctor, if one side was being pulled with 1,000 grams and the other side is in place, wouldn't the body's elasticity allow the side that you say is being held in place to stretch some, to relieve some of that force?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: There are a lot of physiological reactions to mechanical strain. And that is cutting through the tissue. That happens if you have some mechanical load to a textile structure, you have a cutting through and the foreign body migration is known for decades there.

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You have the stretchability of the tissue around that can reduce all this. It can be, yeah, tearing out of some fixation there in this field. So a lot of possible mechanism from the body to release this mechanical strain. Therefore, I said I cannot imagine that 1,000 grams for two weeks, it is imaginable for any part of soft tissue.
BY MR. BROWN:
Q. Doctor, you had mentioned the PVD only requires 600 microns between the fibers to avoid fibrotic bridging; is that correct?
A. PVDF.
Q. I'm sorry, yes. Let me restate that then.
The PVDF only requires 600 microns between the fibers to prevent fibrotic bridging; is that correct?
A. That is what can be referenced by the literature, what is found in this study. And, therefore, this was our cutoff.
Q. Doctor, what was your methodology in determining that PVDF needs 400 less microns -- let me restate that. Strike that.
Doctor, how did you determine that you only needed 600 microns to prevent fibrotic

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bridging for PVDF?
A. I think it was in about 2001 or 2000 when we start to realize that we have a -- or we really get aware that textile structures had a huge variation of pores. And we, for the first time, made this histogram of the different pores. And then there came up the idea to identify at what size of the pores may be sufficient.
And from that time point on, we looked to many, many, many different histological sections, and we measured the distance between the filaments. And we marked whether we saw a bridging or not. And, of course, if you have a small distance of the filaments of 100 microns or 200 microns, so within the staining, you have a lot of different distances between the filaments, because it's cut through the mesh at various locations. And then we started to look all these differences. And the least size where we did not see a bridging, the lowest size, the lowest distance between filaments where we do not see a bridging, that was considered as cutoff.
Q. Doctor, what specific studies can you point to that showed that there was this reduced fibrotic bridging for PVDF that led you to come up

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with you only needed 600 microns?
A. So this is -- so this experience has been used in the publication of Joachim Conze, PVDF as an IPOM in rabbit model, and it's cited in the article from Muhl as well.
Q. That article, Conze?
A. This is -- yeah. I hope so. Or I had to look whether this is one. Conze made three articles, I think, with his IPOM model.
Q. Sir, are you saying that Conze showed that you needed or you could have 400 less microns?
A. Give it to me, and I can --
Q. It's Exhibit 5, so we can both look at it.
A. So there is on page 326, there you see his result concerning bridging, that in the polypropylene mesh, after 90 days in this model, the filament distance of 1,000 microns; whereas, in the co-PVDF mesh, a bridging was always detected below a pore size of 630 microns.
Q. Let me ask you this, Doctor.
And this is a paper that you're a co-author on; is that right?
A. Yes.
Q. Doctor, if you look on page 325, at

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the Table 3, at the bottom, you and I have talked about this yesterday, but the polypropylene total granuloma was 56.4, and the co-PVDF total granuloma was mean 44.0.
Do you see that?
A. I see this.
Q. And so there was a 12.4 difference in granuloma sizes between the polypropylene and the PVDF, is that correct, the co-PVDF?
A. That is correct.
Q. So, Doctor, how is it that a 12 micron distance could change the bridging fibrosis up to 400 microns?
A. I obviously failed to explain that the fibrotic bridging, the formation of scar formation is not completely reflected by the size of the granuloma. After placing of the foreign body there, and as stated by Williams and all the others, you have the foreign body reaction. And this is the ingrowth of some cells. And if you made some histological strainings, you are able to detect these cells. But as well, you have a release of cytocrines, cytocrines, mediators, so a lot of other aspects that, of course, interfere with the local tissue reaction.

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And because of all this together, we don't know in detail what really is responsible for scar -- for inducing this scar formation. But because of all this together, the final result is very simple. You can see in the microscope whether there is a bridging or not. And our first attempt to explain it just by the size of the granuloma, it was wrong. It was not correct. It was not sufficient to predict this histological change.
And this study really confirmed this. It is -- it raises no doubt at the principle that there is a scar formation, but it confirmed that it is quite independent from the size of the granuloma in this model, at rabbit, at mouse.
Q. And, Doctor, if you'll go to page 326, if you look on the second column, I'm looking at the second full paragraph where it starts, "It has been already shown."
Do you see where I'm talking about? Doctor, would you just read that paragraph? Not out loud, but to yourself.
The polypropylene that was tested here had excellent results, is that correct, with regard to inflammatory reaction?
A. This study is a wonderful

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confirmation that polypropylene in a large pore construction causes less inflammatory reaction. And that is exactly what we developed with a Vypro® system, that we thought, it is not sufficient to say polypropylene, but in a specific construction can cause less inflammation. And this is one of the studies again confirming that the construction is of outstanding importance for the tissue reaction.
Q. Now, Doctor, let me ask you this then.
As far as the -- sometimes I might use the word "Prolift®" and sometimes I might use the word "Prolene® Soft Mesh," but I'm talking about the same type of mesh.
Is that your understanding?
A. Yes.
Q. Do you agree that the Prolift® elicits -- strike that.
Do you agree that the Prolift® has an acceptable inflammatory response?
MR. ANDERSON: Objection.
THE WITNESS: From all the measurements from all what we have analyzed, what all what we have looked at, there are -- with the Prolift® mesh in its current form, there are many

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concerns where I'm convinced that a better construction is possible and that a better construction is -- will cause less inflammatory reaction. I have the concern, still the concern, that Prolift® is oversized in comparison to Prolift+M®, for example. And because of this, that there are a lot of or several concerns with the specific construction of the Prolift® mesh in its current form, I think, or I'm -- yeah. My opinion is that it is not acceptable.

BY MR. BROWN:

Q. Your opinion is not acceptable inflammatory response for Prolift®; is that correct?

A. Yes.

Q. And, Doctor, what specific studies can you identify that shows that there is an unacceptable inflammatory response for Prolift®? And as I stated earlier, that includes Prolene® Soft Mesh.

A. I don't know any studies that are in a randomized controlled trial comparing a Prolift® mesh with another, so -- but I know from all these data collections that there are a considerable number of complications after the use of the Prolift® mesh. Despite there is no direct

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comparison with other competitors that may be better, a lot of these complications or some of these complications, not a lot, but these complications can be explained to a large extent by the local tissue reaction to the foreign body material. And that is what we have -- that is my understanding, that this -- or that an impaired tissue integration with a enhanced inflammatory reaction, that this is related to some complications.

Q. Doctor, if you have across the board unacceptable inflammatory reaction, would you not expect widespread complications?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I didn't get the --

BY MR. BROWN:

Q. The Prolift® mesh, if it has unacceptable inflammation, wouldn't you expect there to be widespread or large percentages of meshes with complications?

A. If -- let me answer it with the old experience that we have 15 years ago when we had our experiences with the Marlex® meshes. We saw in some patients, not in all, in some patients some

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complications, migration, inflammation and so on, elevated body temperature in about 30 percent of all these patients. Not all patients with the Marlex® mesh had these complaints.

So the next step was to improve the structure for this. There hadn't been a randomized controlled trial comparing two different things and saying, okay, this mesh is better than the other, but we have seen these complications in these patients that a textile -- a huge textile implant. And then we adopted this mesh. As you know, with the Vypro® we reduced the amount of material. We made the pores larger and got a new device. And then the experience was that we could reduce the number of complications by adopting the requirements of the textile to the physiological requirements.

So it is not -- it has at that time not that every patient with such a device, a Marlex® device at that time, has to suffer from complications; but the risks, the chance to demonstrate some of these adverse events was higher in these than it was on the -- with the new developed meshes. And, therefore, the advantage is to lower the risk there.

And, therefore, I do not expect, and

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I know it from the literature, that not every patient with a Prolift® suffered from erosion. It is not everyone. But I know from the literature and all these reports and data sheets that there are some. And I still believe that the Prolift® -- that in the design and in the structure of the Prolift®, there are several points that are not at its optimum to reduce the risk. That's all -- I've seen recently the presentation of the Project Thunder and Lightning, and I've noticed that everything -- that almost everything that was in this report was reflected in these presentations by Ethicon people as well. So I feel in line with this. It's to address the decrease of the risk for complication.

Q. Doctor, do you believe that the Prolift® has an unacceptable amount of fibrosis?

A. Yes, yes. I believe, because it is not -- or it is oversized. In comparison to Prolift+M® that has been developed, it is oversized, and, therefore, it has a fibrosis which is not necessary, obviously which is not necessary. And, therefore, it is not acceptable.

Q. Let me ask you another way, too. And this goes back to the inflammatory response.

Do you believe that the Prolift® has

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an inflammatory response that makes it inappropriate for use in the body?
A. This general statement, to say Prolift® is inappropriate for the general use in the human body, no, that is not right, because I think there may be some indications. I don't know them, but there may be some indications where you see that the Prolift® may be used in maybe a very tall woman of 3 meter in size or something like this, there may be an indication for them. So I cannot exclude this in general.
Q. Let me ask you that same question for the fibrosis.
Does the Prolift® have an inappropriate amount of fibrosis for placement in the body?
MR. ANDERSON: Objection, asked and answered.
Go ahead.
THE WITNESS: I would make that -- the fibrosis that is induced by the Prolift® leads to an unacceptable risk.
BY MR. BROWN:
Q. And so your testimony is that the Prolift® is inappropriate for use in the body.

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Is that your testimony?
MR. ANDERSON: Objection, asked and answered.
THE WITNESS: Prolift® has an unacceptable risk for the use in the pelvic floor.
BY MR. BROWN:
Q. Doctor, do you believe that the Prolift® has regular bridging fibrosis?
MR. ANDERSON: Objection.
THE WITNESS: I'm sure that, somewhere in the Prolift®, there is some bridging fibrosis. I'm absolutely sure. The question is, to what extent? This is whether it's in the center, whether you see it in the arms. And I don't see any thick picture up to now showing that there is fat tissue in between the filaments of a Prolift®. I've -- in all these documents I have on my computer and I was sent, I never saw it. Where is this fat tissue in the pores?
BY MR. BROWN:
Q. Doctor, what study do you have that shows that there is not fat tissue in the pores for the Prolift®?
A. I can refer to -- I've seen some of the animal experiments Ethicon performed in the rat

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and where two, three filaments is there. And you see that there is -- that the pores are filled with inflammatory tissue. But in fact, of course, yeah, I -- there wasn't not one study presented to me indicating that there was a fat tissue. From all the data I got, I have the impression that in the soft pro mesh that has been tested in the animals, there was usually a bridging.
Q. And is that the 91-day rat study from Ethicon? Is that the one you're talking about?
A. That is one, yeah.
Q. And is there any other studies that you can point to that shows that the tissue did not integrate into the pores of the Prolift® mesh?
MR. ANDERSON: Objection.
THE WITNESS: The fat tissue. I've seen some documents of Deprest and -- but I cannot remember, please correct me if it is wrong, but I do not see any attempt to convince me that there is some fat tissue ingrowth in the pores of the Prolift®.
I know it from Ultrapro®, that you have some of these fat tissue ingrowth there. But from soft pro or Prolift®, I don't know. I've never seen it.

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BY MR. BROWN:
Q. Let me ask you a couple more questions and then we'll break in a second, which is, Doctor, do you believe that there is a mesh configuration that is sold today that is appropriate for pelvic floor repair?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I'm not aware of all of these products that are sold today or of the various techniques where the meshes are used for. There are a lot of combinations, so I think -- or, yeah. You have to do all this work. Characterization of the mesh material, looking for the results and then looking for your indications, and all together then you can say, okay, is the risk higher or lower than the others. So it cannot be answered by a simple yes or no.
BY MR. BROWN:
Q. So, Doctor, are you saying that you cannot identify, as you sit here today, a mesh construction that would be appropriate for pelvic floor repair?
A. I said that I cannot answer your question.

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Q. Is it because you don't know?
A. I don't know all the sufficient what is on the market.
Q. But there's not a piece of mesh that you're aware of that you do know that you would say would be appropriate for pelvic floor repair?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: We have outlined in the report a lot of ideas for the requirement to meshes that are used in the pelvic floor, what has to be looked after. And if you followed all of these ideas, I think you will come up with a better design, with a better construction. If you still have some open questions, may -- it will help to ask the people from Project Thunder. They had a lot of good ideas as well.
So all together, put all together, I have -- I think that we will, maybe we already have, but that we will have better devices. And, of course, there is some indication for meshes in pelvic floor in some patients, of course. That is my vision.
BY MR. BROWN:
Q. And, Doctor, just to make sure you're

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answering my question, can you, as you sit here today, identify by name that you know of a mesh that is appropriate for pelvic floor repair?
MR. ANDERSON: Objection, asked and answered.
THE WITNESS: I cannot stick to the term "appropriate." I can say that, with the FEG, what they -- their constructions tried to consider many of these critical or points that have been identified to be critical for tissue integration. Therefore, I think that the clinical outcome of these devices may be better in the future, but we have to wait on the results of this.
BY MR. BROWN:
Q. Doctor, I want to get you to do something on this piece of paper.
Draw for me, or you can write out filament size, pore size, or you can draw it, whatever works for you, what you believe is the appropriate mesh construction for pelvic floor repair.
MR. ANDERSON: Objection. He's not going to do that. He's provided you with a 70 page report and two days of testimony to be able to tell you what he believes the optimum pore sizes are.

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You can ask him those questions, but he's not going to commit to a graphic drawing to enable you to use that as an exhibit when you have him for two days and all of this material. Not going to do it.
MR. BROWN: So you're refusing to allow him to answer this question?
MR. ANDERSON: You bet. Well, I'm refusing to allow him to start to draw for you what he considers to be the perfect pore. You bet.
MR. BROWN: And the mesh construction?
MR. ANDERSON: And the mesh construction. You bet.
MR. BROWN: All right.
BY MR. BROWN:
Q. Doctor, then, tell me then what would be the filament size that would be most appropriate for mesh construction?
MR. ANDERSON: Objection.
BY MR. BROWN:
Q. Let me strike that question right now. Let me ask something.
Are you able to draw a mesh construction that would be appropriate for the pelvic floor?

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MR. ANDERSON: Objection.
THE WITNESS: Definitely not. Coming to a design for a mesh for the pelvic floor, it's a process. It includes a lot of different things, a lot of different models. It's a work. A lot of people have to come together and bring in their expertise. And then finally you get -- have a -- the best product that is possible in the moment. That is the aim we can have.
If you asked me which size of the filament, first of all, it depends on the polymer, what you want to have. Then it depends from the pore size you can realize with this specific filament, because this filament is limited in its tensile strength. If you need, you need some tensile strength, you need a little more of these filaments. Then it depends of the tissue reaction to the surface and to the curvature of the filament. If it's too small, then you have a stiffness of the cells so that they cannot come in close to this surface. We are still not sure whether the Vypro® with the five polypropylene filaments really was a bad choice. It has some disadvantages for the surface of the bacteria adherence, but if you look to the foreign body granuloma size to the filaments

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of the Vypro®, you see that they are very small. And even all together, these five are less than one monofilament of a similar thickness would have been. So maybe it is the best option to realize the elasticity, stretchability of a mesh, porosity of a mesh, a construction made of three filaments is better than of one. Maybe it's 12. It has to be, yeah. You have to work on it and find the best solution in comparison to others. You have to test all these. Try a thick one, a thin one and then adopted it. That is the way that we have learned with the Vypro® to come to a better mesh.

MR. BROWN: Take a lunch break.

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(A luncheon recess was taken from 12:20 p.m. to 1:13 p.m.)

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BY MR. BROWN:

Q. Doctor, we were talking a little bit about mesh characteristics.

Do you have a filament size that you think would be optimal for a piece of mesh?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: From our experience,

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looking to the tissue section after incorporation, I think that a size below 130, 150 microns will offer most advantages in regards to the handling or how to make the constructure and offers most options to be less there. Whether there is a minimum of 50, 60, there is insufficient data to come there. And it depends, of course, from the intention where you place, and so what you want to have by this.

BY MR. BROWN:

Q. Doctor, I'm going to ask you about a couple of characteristics. And I'm going to be asking you about the pelvic floor.

So with this below 130 to 150 microns for filament size, is that an appropriate filament size for the pelvic floor?

MR. ANDERSON: And, again, objection.

Go ahead.

THE WITNESS: I have no information that it is a -- that it cannot be or that is not applicable to the pelvic floor.

BY MR. BROWN:

Q. And, Doctor, when we were looking at the Jan Deprest article, one of the measurements he looked at was the thickness.

And what is an optimal thickness for

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a mesh used in pelvic floor?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: The thickness or the definition of whether it's optimum for the tissue ingrowth and for the function, what is the best thickness to achieve this purpose may differ. It depends from the indication. It depends from the size from the configuration. So there are -- in -- for the abdominal wall, there are some devices that are intentionally constructed in with a three -- in a third dimension, to get more thicker devices, to have more -- to have another integration into the tissues by these three-dimensional form of these things. There are other three-dimensional things, as plaques in the abdominal wall, which behave, again, differently.

For the pelvic floor, I do not know any specific investigations, what part of the reinforcement of the tissue should be done by three dimensional or by a specific three dimensionality of this device. So to my knowledge, there is no intention to construct real three-dimensional devices. However, every mesh that we are talking about has, of course, a third dimension, as

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everything in this world. And, therefore, again, we have a limitation of all characterizations of the mesh material by this third dimension.

BY MR. BROWN:

Q. And --

A. So your answer has been whether there is an optimum of the thickness. No, there is no way to define this in the moment on the basis of my knowledge and what I know.

Q. Doctor, as far as the density or the weight of the mesh, grams per millimeter squared, that way we're all talking about the same thing, is there an optimal range for the weight of a mesh in the pelvic floor?

MR. ANDERSON: Objection.

Go ahead.

BY MR. BROWN:

Q. You're welcome to look at the article that I was looking at if you want to.

Or do you need that or not?

A. No. I just to think, to find the words.

Q. Okay.

A. There is no optimum weight of anything, because the property of weight of a

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textile mesh is not able to reflect the specific properties of a textile.

Since the study from Weyhe, Weyhe, we already talked about, it is very clear that even with the reduced amount of material, you can produce awful meshes or mesh-like structures. And, therefore -- and we know that PVDF has a specific weight that is double as high as polypropylene. So with PVDF alone, you create some heavy textile structures, which can be excellent. So it doesn't depend from the weight, and, therefore, you cannot specify an optimum mesh by weight.

Q. Is there a range of weight which you can identify that would be appropriate in the pelvic floor?

A. No.

Q. And, Doctor, is there a filament type that you believe that is optimal, meaning multifilament, monofilament or something in that neighborhood?

MR. ANDERSON: Objection, asked and answered.

Go ahead.

THE WITNESS: As we already talked about, monofilament has the advantage to have a

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reduced surface in comparison to multifilaments. That is of specific importance for the adherence of bacteria. There are some constructions with some filaments in between as for the Vypro®, so this type of olgoliofilaments, although this term has not been defined officially in the literature, therefore, it can be evaluated or justified only in the context of the many different functions and characteristics of textile constructions.

BY MR. BROWN:

Q. And, Doctor, is there an optimal pore size for meshes in the pelvic floor? And that can include a range, if you have a range.

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: As for the other characteristics, there is no specific value for a best pore size for the pelvic floor as well as for other tissue organs. We know that there is a critical minimum which should not be -- we should not go under this critical minimum. Whether there is an advantage then to expand the number or the pore size even more, with a Vypro®, we have 3 to 4 millimeter. That has to be tested in the specific condition where the device is used for the specific

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indication, because finally it's a compromise between the surface, the tensile strength you want to have, the elasticity, the stretchability of the mesh you want to have and the filament you can use, the polymer you can use. And if you take all this together, then you will come to a pore size that is the best compromise to fulfill all this.

BY MR. BROWN:

Q. And, Doctor, do you have or can you now tell me what would be an optimal mesh using each of these characteristics that we've talked about and any other characteristics you want to discuss?

MR. ANDERSON: Objection, asked and answered.

BY MR. BROWN:

Q. I'm talking -- let me restate.

Can you give me specific numbers or specific types of polymers for each of these mesh characteristics to tell me what might be an optimal mesh for pelvic floor repair?

MR. ANDERSON: Same objection.

Go ahead.

THE WITNESS: I can define some critical points to come to an optimum mesh configuration for the use of the pelvic floor that

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has to consider a high structural stability. That means that you should avoid a collapse of these pores. That should -- we need textile structures that have the least amount of surface that is possible under consideration of the biomechanical situation, where it's placed, because every reduction of surface will reduce the possibility of bacteria to get attached to the surface. And even a reduction of the surface by 30 percent may be beneficial to lower the risk for bacterial infection, as this device is used in a contaminated field, in contrast to all these devices that are used in the abdominal wall cavity.

So this is another point that should be considered when looking to the optimum device. If you're looking to the polymer, you have some more options with the PVDF than with the polypropylene, but it does not mean that it is excluded that -- or the polypropylene mesh, you construct a device with an acceptable risk or the best risk there. But, again, with the PVDF you have more options to modify the textile construction to this.

The -- as Professor Williams pointed out, every device has to consider the balance of its stretchability to the surrounding tissue, of course.

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And every device has to withstand a minimum tensile strength, because it is implanted as reinforcement of the tissue, and, therefore, there -- it has to withstand this.

So these are, again, requirements a good mesh has to fulfill. And, of course, we need a low inflammatory reaction, acute, but as well chronic. We need low tendency for migration, erosion, integrating pain in scar formation. All this has to be considered as well.

BY MR. BROWN:

Q. Doctor, is it fair to say that all these considerations have to be taken in, but as you sit here, you can't go through each one of those characteristics and say, this is the precise weight, this is the precise pore size, this is the precise polymer; is that correct?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: It is correct that you cannot give a certain figure and say, okay, we fit to this figure and the result will be excellent. It is always a consideration of risk. Every textile construction is a compromise. It has to be a compromise, and you have to compare the risks

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between different constructions or possibilities of constructions.

BY MR. BROWN:

Q. Doctor, can you go through each one of the characteristics on the Prolift® and identify where you find fault with the construction?

A. We can go through the report, page 1 and following.

Q. Doctor, let me go ahead -- because I know you're trying to read through it. Let me see if I can ask some more specific questions and see if that helps you to answer the questions.

A. The problem for me, so that you understand it, is I have to extract those things.

So I just reflected whether it's the best way to go to the titles or to go to some paragraphs, but maybe it's a better option if you are putting one of these aspects and then we talk about this.

Q. I just didn't want you to go back and relook all through your report. But let's try it that way and then I'll give you an opportunity to expand.

Doctor, do you find fault with the filament size of the Prolift®?

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A. As in the past minutes, we tried to -- or I tried to explain that there is not a single value that can be defined as being optimum. But you have to consider it in the whole -- the constellation of all conditions together to define whether some of these things are optimum or not in an optimum shape.

Q. Then it might be --

A. Therefore, the question from you to ask me whether there is a mistake in the filament obviously demonstrated that I failed to explain this to you. So, again, I would like to say that it is not possible to define the optimum size of the filament, and, therefore, it is not possible to say that a certain size of the filament is, per se, a mistake. The 87 microns, 86 microns, of the size of 86 microns used for the Prolift® can be acceptable in the consideration of all other conditions.

Q. I think, Doctor, we're probably going to have to go back to my other question then, which is, in consideration of the Prolift® mesh as a whole, what characteristics do you find or have -- strike that.

With the Prolift® mesh, as a whole, what characteristics do you find fault with?

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A. So major. Let's start with some major points. First is if you -- if you consider that surface is critical for the risk for infection and the risk for an overwhelming or an inappropriate inflammation in the local surroundings, then you have a certain surface in the Prolift®. If you compare this with the Prolift+M®, which is reduced in weight, you have a reduction in the surface with the Prolift+M®.

I think a reduced surface of a device is better and may decrease the risk for infection. Therefore, I believe that the Prolift® has a surface which can be reduced at least to the level of Prolift+M®, and, therefore, that would mean a reduction of 30 percent, so that may be followed by a reduction of less bacterial adherence to the surface. That should have been a point that should have been investigated.

Of course, the surface depends on the mechanical strain. You have to compensate with this design, and, therefore, you have, first of all, to define the biomechanical requirements. And then you're able and -- you're not able, but you're forced to do so, to reduce the amount of material to reduce the surface to the least level that is

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possible to fulfill these functional things.
Then you get an impression how much surface you have, how much tensile strength, what filaments you may need to fulfill this functional task. And then you have to look to the pore size, because this later on is followed by -- is associated with clinical outcome and clinical complications. And, therefore, you have then to decide how to realize this functional demand. And then you are coming to a textile construction providing a pores. And then you have to consider that this or at least part of the mesh has to withstand some mechanical force, has to provide us structural stability. This is the process that has to be followed.
Q. Doctor, I'm with you on the process. Just tell me what's wrong with the Prolift® on those processes. Just include that in your answer.
A. The Prolift® has too small pores.
MR. ANDERSON: Too, T-O-O?
THE WITNESS: (Witness nods head.) Yeah, too. Yeah.
The pores of the Prolift® show collapsing under strain. Too much surface, too small pores, structural instability. There are

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other aspects that is this particle loss that is the frizzling, if you cutted it. That is a disadvantage if this appears. I know it from former times, the Marlex® was an awful mesh, because you have a lot of powder when you trimmed the mesh during the OR. So this is a characteristic that should be avoided, not to have these small particles in the area of the wound.
I'm not sure, I don't know, I don't see sufficient information what is the bacterial adherence to this material in the pores, whether it can be optimized or not. And stretchability, in principle, the Prolift® mesh is done with -- as an extraction of a flat mesh. So there is no specific design for the arms of or the flat mesh area. There is no specific orientation of the fibers as well.
So I did not see any specific optimization, which means not only optimization for the manufacturer but optimization in regard to the risk for the patient. I did not see any optimization specific adaptation of the structure to the needs that has been defined before. And this is what I just referred, I find it exactly in a lot of presentations by Ethicon people as well.
BY MR. BROWN:

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Q. Doctor, when you say the optimization of the mesh, does that mean that it's not cut in a manner that optimizes facilitating the pelvic organ prolapse? Is that what you're saying?
A. Optimization, first of all, means optimization in regard to the risk of the patient. Optimization for the textile structure, you have to define, you have to be aware that a complex structure and configuration of the Prolift® is with the three-dimensional positioning in the tissue with the arms there, that there are different strains for the different parts of the meshes. It should be assumed that it is like this. And, therefore, you should provide a textile structure that reflects these differences in the demands, always optimized to the risk of the patient.
And when I am looking to the arms of the Prolift®, then this is cut, just only cut from big piece of meshes, and the textile properties differ in the arms every centimeter, because the course of the wall fibers differ every centimeter. So it is impossible to really -- yeah. It is already impossible to define the elasticity of the arm in what part. And to optimize it to the tissue demands, it is impossible as well.

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Q. Let me ask you this, Doctor.
Is the shape of the Prolift®, the way it's cut, is that in an optimal configuration to prevent pelvic organ prolapse?
MR. ANDERSON: Objection.
By the way, he's not here as a surgical expert to talk about whether or not it can prevent pelvic organ prolapse. If you want to ask him whether or not, as he just answered, whether or not the textiles are designed in a manner which could reduce complications, that's one thing. But asking him if it's cut in a way that can prevent pelvic organ prolapse, he's not here to answer that question. That's a urogyn question.
MR. BROWN: Let me ask you this, so that I'm clear on that. And this is you and I talking on this.
MR. ANDERSON: Okay.
MR. BROWN: But one of the adverse effects that could be from pelvic organ prolapse for mesh is recurrence. So that's a complication.
So are you saying that he's not here to talk about the complications of Prolift®?
MR. ANDERSON: No, not at all. I'm saying that he's not here to talk about whether or

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not this design prevents pelvic organ prolapse or whether it's the optimal design to prevent pelvic organ prolapse. He can talk about whether it's the optimal design in the tissue and the way that the body will react to it and the way -- the biomechanics of it, all the things he's been discussing.

And I think he just addressed that, which was the position of the warped fibers and the elasticity and things. But to say that he's going to be an expert on whether or not this mesh helps prevent pelvic organ prolapse is quite different.

MR. BROWN: Is he an expert that's going to be able to talk about how the Prolift® causes complications like erosion in the pelvic floor?

MR. ANDERSON: Sure.

MR. BROWN: I think that's a very fine line --

MR. ANDERSON: It is, but I want to make sure that we understand that preventing pelvic organ prolapse is different from whether or not the mesh design and construction may lead to erosions.

MR. BROWN: I disagree, but we can agree to disagree.

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MR. ANDERSON: Okay.

MR. BROWN: Well, let me just -- can you restate my question, please, Ann Marie?

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(The court reporter read the pertinent part of the record.)

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MR. ANDERSON: So same objection about preventing pelvic organ prolapse.

THE WITNESS: The manifestation of a recurrence depends from many different things. And as it was said, I'm not an expert of these technical things or the technical specificities, how to make it, how to place it, and most of all, to find the best indication for doing this one. But if you are considering recurrence as a readout, there are several different definitions of recurrence. And I never read, through all these articles, that one recurrence was done by a ruptured -- central rupture of a Prolift® mesh. Never again. So this confirms my impression that the Prolift® is considerably oversized, overengineered.

BY MR. BROWN:

Q. So, Doctor --

A. So otherwise around, if I have had

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the notice of someone who said or some group of patients where they got their recurrence because the Prolift® ruptured in the center, okay, then I would say that is the course of this. And, therefore, I'm still convinced that it is overengineered. I have the concern that it is overengineered.

Q. But, Doctor, you would say that it has sufficient -- restate. Or strike that.

The Prolift® has enough force -- strike that again. I'm sorry.

The Prolift® has enough strength to prevent pelvic organ prolapse. You'd agree with that?

MR. ANDERSON: Same objection, but go ahead.

THE WITNESS: The difficulty is that there are several reasons for getting a recurrence of this. Again, I have to refer from our first experience with the Marlex® mesh. Everyone who sees the picture of an explanted Marlex® mesh knows a strong scar plate. It is impossible to cutted it and to tear it off, impossible. However, these patients got recurrences at the neighborhood of these textile structures. So the biggest scar plate, the strongest mesh is not obligatory able to

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prevent any recurrence. This is a too machinistic view of the things.

BY MR. BROWN:

Q. So you're not saying that the Prolift® is not strong enough.

Do you agree with that?

A. I agree that the Prolift® is not very -- not strong enough to -- yeah. To prevent what?

Q. Well, let me make sure you're hearing me right and we're saying the same thing, make sure it comes out clear.

Is that you're not saying that the Prolift® is too weak? You agree with that?

A. For using as reinforcement in the pelvic floor, it is not too weak, with double O. Yes.

Q. Okay.

A. Yes, total agreement.

Q. Let me ask you a couple questions about degradation.

How do you define degradation?

A. Degradation, degradation is a loss of integrity, I think, if these are the right terms. And usually it is seen with a degradable, absorbable

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material. There this is the term where it describes that you have a loss of integrity with it sometime.

Q. What does a nonabsorbable mesh fiber look like that has been degraded?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: That has been degraded?

BY MR. BROWN:

Q. Yes.

A. Yeah?

The first appearance that we have for the degradation of a so-called nonabsorbable mesh material, that has been the polyester. There has been a polyester mesh explanted in the '90s where we saw a marked degradation, a complete degradation of the filament, broken down to hundreds of parts of small particles. This has been frequently published. So for polyester, we got this early experience by light microscopy. We later on noticed that the different layers of the PTFE, mainly by studies from Zimmermahar, from Ustritch. He first showed in his experiments that the PTFE layers are showing this degradation.

We believed, until the beginning of the last decade, so 2000 ongoing for the next years,

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we were convinced that polypropylene does not show these signs of degradation and had a lot of severe discussions with the people from Covidien. They said always polypropylene is going to be degraded but polyester not. And so we always said, no, polypropylene is inert, it is stable, it does not show these sorts of degradation. And it has been on the market for 45 years and we don't know. So we were convinced that polypropylene will not cause any problems.

And then -- so about 2000, where when we started to think about PVDF, we got some information that it may be not like this. And then Clave comes up and Ramshaw comes up with their electron microscopy pictures.

And you have to know that all these histological slides, the microscopy is not able to detect any different degradation, because usually in these slides the mesh material is not seen. It is removed by the cutting. So it is hardly possible to see any degradation by light microscopy. You have to do some electron microscopy, which is expensive. So, yeah.

But with the publication of Clave and from the American group showing electron microscopy,

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then we got aware that maybe -- that there is a surface cracking after integration into the tissue. And we, I think last year, or last year, Klosterhalfen did -- made some electron microscopy from human explants and saw this cracking as well. And I know an image from the FEG where they made an electron microscopy from an explanted mesh material from a rat. And, interestingly, this material consists of a PVDF thread and a polypropylene thread in one. They have a product which contains a polypropylene thread. And if you're looking to this electron microscopy, you see a surface cracking on the polypropylene fiber but not on the PVDF fiber.

So when I put all this together, I think the evidence that there is no degradation of the polypropylene threads in a mesh is considerably lowered.

Q. All right, Doctor.

A. At least to say.

Q. When did you come to the conclusion that there's a possibility that polypropylene might degrade? What year?

A. What year? It has been -- I think we have been either in Nuoro or Nice. I do not remember the -- I always mix it up a little bit, but

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we have been on a conference of urogynecologists and where this data from Clave has been presented on this conference, 2008, 2009.

Q. So sometime around 2008, 2009 approximately is when you came to the conclusion that polypropylene might degrade; is that correct?

A. And that it is coming to be -- or is going to become a concern, yes.

Q. And, Doctor, are you aware of some polypropylenes having an antioxidant resin that's mixed into the polypropylene?

A. Yes.

Q. And does Ethicon's mesh have that antioxidant polypropylene resin mixed together?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I've read it in the documents. Usually we don't know whether there are some additives that usually are added in very small amount of material, whether this is added. And usually the manufacturers are the people coming to us and demonstrating their products, they don't know it. So we always try to get the information whether the polypropylene of Atrium or polypropylene of Bard, Marlex®, was different to that of Ethicon, but

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we didn't -- we never got this information, so -- but I know there has to be additives in the polypropylene. To my knowledge, this is not necessary for the PVDF. PVDF can be used as a pure form.

BY MR. BROWN:

Q. Doctor, I'm just talking about polypropylene right now.

A. Yeah, just for the knowledge. But for the polypropylene, I know there are several additives.

Q. Now, Doctor, as a scientist, have you studied it to be able to come to the conclusion that a polypropylene does in fact degrade currently?

A. Does not or --

Q. Does degrade. So I'll restate my sentence.

As a scientist, have you come to the conclusion that polypropylene degrades based upon your studies?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Yes, yes. It shows signs of degradation. That is my current opinion to this.

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BY MR. BROWN:

Q. And have you specifically studied that, Doctor?

A. We didn't initiate any systematic investigation to look to this.

Q. And, Doctor, do you remember on the Costello study that you cite in your paper, do you remember that being a Bard mesh, a Kugel Composix?

A. I remember.

Q. And in both Clave and Costello, neither one of them show an Ethicon polypropylene mesh that is degraded; is that correct?

A. We have to look. For this specific question, we have to look to it.

Q. Doctor, let me ask you this and then we might look at that article.

If the Clave and Costello articles do not show that an Ethicon polypropylene mesh is degraded, are you convinced today that an Ethicon polypropylene mesh can degrade?

MR. ANDERSON: Objection.

THE WITNESS: It is very clear if they didn't really show that an Ethicon product of polypropylene with some specific mixture does not show a degradation, or if they didn't use this one,

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you cannot argue that the degradation of an Ethicon product is confirmed by these studies. That can be said by this. But I've read in the documents that when getting notice of this principle that polypropylene, and in the '90s, polypropylene generally has been regarded as being inert and not substance for degradation, generally, not specific for some additives or something like this.

So when the data coming up showing that polypropylene, in some forms, ever show some sort of degradation, that should rise a certain concern. And I've seen in some documents where someone is saying it is just an artifact. And we don't have -- think further on and make other studies about it and look after it, because it is an artifact and we did some other studies showing different things.

I have objection to this procedure there. So you may be right and it would be a good thing if the Ethicon polypropylene products do not show this degradation after incorporation, yeah. And I think it is quite necessary -- it is necessary to make several electron microscopic investigations and to demonstrate that you don't have this surface cracking at the surface of your products. This is

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not -- it should not be required only for pelvic floor, but for the guys with abdominal hernia, it will be interesting to know as well whether the Ultrapro® or the Prolene® shows some surface cracking on the polypropylene part as well. This is my opinion to this as a scientist.

BY MR. BROWN:

Q. Doctor, do you agree that Ethicon could rely upon your statements when you wrote them that the polypropylene did not degrade?

MR. ANDERSON: Objection.

THE WITNESS: In what article, at what contents, to what time period?

BY MR. BROWN:

Q. Doctor, in 2004 you stated that polypropylene has no tendency to degrade.

Is that something that Ethicon could have relied upon?

MR. ANDERSON: Objection.

THE WITNESS: What do you mean by rely on it? I do not understand this rely on it. Does it mean that they can say, because these people say it in their article, we can be sure that? Then this is obviously not justified, because we did not make own investigations to the polypropylene at that

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time point. I've told you, we relied, we relied on information from the manufacturer, from the companies, that polypropylene did not show this. And at that time point, we didn't have, though we looked, we didn't have in the literature indications that it was different at that time point. And, therefore, this was mainly written in the introduction to show the differences to the polyester and to the PTFE. This sentence should not -- if this sentence is used as a guarantee for a manufacturer to use this product, this polymer, this would be a hazard, if I find the right word.

BY MR. BROWN:

Q. Doctor, if you look at your expert report on page 11. I'm looking, Doctor, in the second full paragraph, where it says, "The clinical implications."

Do you see that?

A. The third paragraph, "The clinical implications of a degraded"?

Q. Yes. Where it says, "The clinical implications of a degraded, oxidized surface of" polypropylene "mesh fibers in human tissue are not completely known."

Do you see that?

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A. I see this.

Q. And so, Doctor, it's your opinion that today we do not know what the implications are of degraded polypropylene; is that correct?

MR. ANDERSON: Objection.

THE WITNESS: We did not fully know the clinical implications of this. I -- for my understanding of many biological processes, I'm sure this is a nonlinear process. Degradation of a polymer is a nonlinear process. And this is true for the degradable, where intentionally there has to be a degradation, but it should be true for the nonabsorbable materials as well. So nonlinear process means that maybe sometimes in 20 years there may be an explosion, there may be a complete degradation, an exponential increase of surface in this field, and then you have to consider what happens there.

If you have this exponential increase of surface maybe in 20 or 30 years, I cannot excluded it. But this is my concern in this. But today it is right that in the moment, we don't have a full understanding what is the clinical relevance. It would be too rough to correlate this surface cracking to some specific complication there. I

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would have -- I would see some problems to correlate this. But it is a concern on the longhand, and it gives or indicates the level of investigation.

BY MR. BROWN:

Q. Doctor, I believe what you're saying is the -- you cannot say what degradation occurs might lead to a particular complication; is that correct?

A. I cannot give a precise figure, either what type of complication or to what extent this surface cracking contributes to the up -- to the manifestation of a recurrence. If you have -- if this will lead to an increased surface of 30 percent after ten years, then if we have these data, then it will be more easy to get a precise risk assessment.

Q. And, Doctor, you don't have any data today that says that the Ethicon polypropylene increases its size by 30 percent in ten years, do you?

A. No, I don't have the data.

Q. Now, Doctor, in your report, you identify what's called a barbed wire.

Do you see that?

A. Yeah.

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Q. Doctor, do you have any clinical information that shows that the Ethicon polypropylene leads to a barbed wire?

A. This barbed wire is a model. It is a model on the cellular level. It is the consequence on the cellular level what happens. If you have an increased surface, if you have these -- if you look to that very sharp edges at that area, this should lead to an activation of the cells that are attached to it. On the clinical level, I don't have any data.

Q. And so you're saying the barbed wire is not the actual polypropylene but it's some kind of cellular structure?

MR. ANDERSON: Objection.

THE WITNESS: No, no. If you look through the electron microscopy, you can see the cracking in the surface, but this will lead to an activation, to an irritation of the adjacent cells, because you always have to consider some movement, some motion in this area.

BY MR. BROWN:

Q. And, Doctor, but there's no clinical evidence at this point that Ethicon polypropylene leads to this barbed wire effect; is that correct?

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A. There is no clinical study confirming this on the clinical level.
Q. Doctor, you continue down a little bit further, and you say that this degradation could cause an increase in inflammatory response.
Do you see that?
MR. ANDERSON: The paragraph starting "Furthermore"? Is that where you are?
MR. BROWN: I mean generally.
MR. ANDERSON: Oh.
BY MR. BROWN:
Q. Doctor, generally, are you talking about that degradation could lead to an increased inflammatory response in your expert report?
A. Degradation, increased surface, leads to an intensified inflammation, yeah.
Q. Doctor, is there any clinical data that an Ethicon polypropylene increases its size and leads to an increase in inflammatory reaction?
A. Not to my knowledge.
Q. Doctor, if we look to the -- it's two paragraphs down where it says "Finally, bacteria."
Do you see that section?
A. Uh-huh.
Q. Doctor, do you have any clinical data

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that bacteria can get into the cracks of degraded mesh and increase the risk of infection?
A. I know that the risk for infection in the presence of a biomaterial is a considerable concern. So there is general a concern, or this is a major complication in this field, and there is quite good evidence that this is related to the surface of the material. As I tried to point out is we have very little information about surface cracking of Ethicon polypropylene products. There are few investigations, few images of it. And I don't -- yeah. I don't remember whether there is a specific study showing if Prolift® shows this degradation. But I didn't see any study excluding this, this potential risk for the patient, so --
Q. Doctor, I want to get you out of here by 5:00. Okay? So I just want to --
My question to you is, is there any clinical data that shows that bacteria gets in the degraded mesh and leads to infection?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I don't find the combination clinical data and bacteria to see this, because in clinical data on the clinical level, it

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is impossible to find any bacteria.
BY MR. BROWN:
Q. Doctor, when you take a piece of Prolift® out of the package, is it frayed to some extent on the corners?
MR. ANDERSON: Objection.
THE WITNESS: When you take -- so frayed means frizzled, sharp corners at the edge?
MR. ANDERSON: You call it frizzled, we call it frayed.
THE WITNESS: Frizzled? Frayed?
Yeah, there are some areas where you have ends of filaments going to the border.
BY MR. BROWN:
Q. Doctor, have you cut pieces of mesh before for hernia repair, polypropylene meshes?
A. Yes.
Q. Doctor, are you aware of the places where you cut the polypropylene, that that has caused an increased inflammatory reaction?
A. Again, please?
Q. Sure.
Where you have cut a polypropylene mesh and placed it in the abdomen for a hernia repair, are you aware of it leading to increased

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inflammation where you cut it, the mesh?
A. We are aware that we have -- that there are differences between the different materials, whether they made this -- this creates this particle when trimming. There are differences, so it depends from the textile structures whether you have a lot and whether you don't have a lot. And our experience was that the old Marlex® mesh showed an extreme production of these small particles in the OR field. Of course, we didn't made a revision operation after two weeks or just could relate it to this particle loss in these patients if they got some inflammatory response.
So the reduction of the inflammation to this -- to these particles alone is hardly -- is hard to be verified in clinical studies or even in experimental studies. However, if -- there is good evidence that the degree of tissue inflammation depends on the surface to the foreign body. And the higher the surface and the more foreign bodies, the higher the intensity of the inflammation and fibrosis there. But there is no absolute level.
Q. Doctor, do you have any clinical evidence that when the Prolift® mesh is cut, that the sides that are cut cause an increased

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inflammatory reaction?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: For the tissue or -- there is no specific -- there are no specific data, to my knowledge, that are able to separate the overall tissue reaction, the effect to the material and to these lost particles by cutting through, which is -- I don't know any study which is able to separate these effects.
BY MR. BROWN:
Q. Doctor, when you place a piece of mesh in an animal, you cut the mesh and then place it in the animal. Correct?
A. Usually that is not right. In most of the studies, with Ethicon as well, we got the mesh materials presized or pretrimmed or in the definitive configuration, because then they were packed for experimental use in the appropriate size, and then they went to the sterilization. So in most of our experimental studies, we did not trim it during the OR.
Q. Doctor, did you ever trim a piece of mesh, an Ethicon polypropylene mesh, and place it in an animal?

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A. I do not remember if in any of these experiments it was necessary, because, as I said, we always got it packed in 2 to 3 centimeters sample size there.
Q. Well, Doctor, if it comes already frayed and frizzled, as you've stated when you implanted it, it would be frayed and frizzled. Correct?
A. Please explain frayed and frizzled, what you mean, in detail.
Q. Well, I want to make sure that I'm using your words correctly. And you talk about -- if you look on page 47 of your expert report.
Do you see on the top it says "Fraying"? Do you see that heading, Doctor?
A. Fraying, yeah.
Q. What do you mean by fraying?
A. Fraying is a -- what we have been -- learned from the Marlex® mesh, that you have a -- several small particles that appear during -- maybe appear during the manufacturing process but which of course occur when you trim the mesh, because you have to cut the linkage of the textile. And it depends from the textile structure and from the linkings how much of this fraying will be the result

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of your trimming there.
So there are mesh configurations that produce only little fraying, and there is others that produce more of them. And this is -- I know this is investigated by Ethicon as well, and, therefore, they switch to laser cutting of the mesh instead of mechanical. But in the OR, you don't have the laser to cut it and to trim it, and, therefore, you should be aware that this happens and you should try to control the amount of fraying that may occur after -- when trimming the mesh.
Q. Doctor, when you have a pore and then you go and you cut that pore and it's got a little piece of that fiber sticking out, is that what you're saying is fraying?
A. It is -- yeah. This fraying consists of different particles. Some are some small particles spreading out from the polymer and some others are the remaining fibers which are cut through and then lost.
Q. When you take a piece of Prolift® right out of the package, is there any fraying on the side of the Prolift® mesh as it comes out of the package?
A. This is written in his report there

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that there are some -- always there are some small particles.
Q. So when you got it precut and sent to you and placed in animals, it would have already had fraying on it. Correct? Let me restate that.
When you got mesh that was sent to you precut, then it would have already had some fraying. Correct?
A. It may. But it depends from the textile you have. There are some without and some when it has a very firm linkage, then it does not tend to lose so much material. And, therefore, it may be that you have a mesh that has only very little amount of fraying.
Q. Doctor, for the Prolene® Soft Mesh when it comes to you precut, there's going to be some fraying.
Is that what you're saying?
A. There is some fraying.
Q. And when you place that in an animal and tested it, can't you look to see if there's a higher inflammatory response on the edges?
A. To investigate whether the fraying has an effect there, then you would have to make another experiment then. You have to compare the

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Prolift® without fraying and then add some fraying on it and then look what is the biological consequences for this. This is the fraying.

The frizzling, this sharp edges at the border of it, there are some devices which closed the border by just putting in some filaments so that you don't have these sharps edges there. This may be an alternative. You can do some testing comparing these two, but this mainly depends from the mobility of the tissue. So sharp edges in a tissue which does not show this mobility will not do likely so much harm as in an area where you have a lot of mobility.

Q. Doctor, can't you compare, in the middle of the mesh where there's not any fraying to the corners of the mesh and decide if there's higher inflammatory response where the fraying is occurring?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: It is very difficult, yeah. You may have a look to it, but this would interfere with the surgical trauma, which is different to the sides as to the middle. This depends of the shearing stress. So if you have in

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the tissue that is without mobility, then you have another thing. It depends from the tensile strength. If you have a collapse of structures, then you have an intensified inflammatory reaction in the middle, not at the border. So, yeah, there may be or I have no problems to design several experiments studying this phenomenon and the relevance for the biological outcome. I have no problems to make this design. But I'm, again, not a manufacturer.

BY MR. BROWN:

Q. And, Doctor, let me ask you this.

Do you have any clinical studies or preclinical studies that shows that the fraying of the Prolene® Soft Mesh elicits a higher inflammatory response?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Again, inflammation/infection is a clinical concern based on clinical complications, and I don't know any study that can differentiate the impact of fraying, particle loss, surface, to separate all these different impacts. I don't know any possibility to do so, and I do not have any data that are able to

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separate this clearly.

BY MR. BROWN:

Q. Doctor, are you saying that there is no preclinical or clinical studies that shows that the Prolene® Soft Mesh where it frays elicits a higher inflammatory response?

MR. ANDERSON: Objection, asked and answered.

Go ahead.

THE WITNESS: I am not sure whether I get all these combinations in your sentences right.

BY MR. BROWN:

Q. Do you have any clinical or preclinical studies that shows that the fraying of the Prolene® Soft Mesh increases the inflammatory response?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: As I have said, I have no data that identifies the separate impact of the fraying to the inflammation.

BY MR. BROWN:

Q. Okay.

A. Neither clinical or preclinical.

MR. BROWN: I know we've been going

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for a while, so let's take a break.

MR. ANDERSON: Sounds good.

- - -

(A recess was taken from 2:27 p.m. to 2:42 p.m.)

- - -

BY MR. BROWN:

Q. Doctor, let me go back to degradation just for a little bit.

Is it your understanding that if a mesh does degrade, that some free particles could come off of the mesh fiber?

A. Degradation, yeah, means or will offer the option to -- that some particles are separated from the filament and, therefore, means increase of surface.

Q. So when you're concerned about a potential inflammatory reaction, is it because of the increased surface or is it because of potential particles that come off the mesh fiber?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: When there is a release of particles going to be separated from the filament, then you have an increase of the surface.

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And the local inflammatory reaction so far I understand is influenced by the surface in general, as well as the relative movements of particles to this tissue. And all together, this -- a considerable -- this balance of the mobility there and enhanced surface that has to be considered as a risk factor and not as a beneficial aspect.

BY MR. BROWN:

Q. Doctor, are you aware of any clinical data on the Prolift® allowing any free particles to come off the mesh and elicit a higher inflammatory response?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I know that there is a release of particles when trimming the Prolift®, not only from our investigations, but from the documents from Ethicon themselves. To my knowledge --

BY MR. BROWN:

Q. Doctor, do you understand my question? And I'll ask you about the trimming.

A. Yeah, yeah.

Q. But mine is just about particles that may come from degradation.

Do you want me to restate my

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question?

My question was, are there any particles -- scratch that.

Are you aware of any particles that come from degradation that lead to an increased inflammatory response for the Prolift®?

A. I have insufficient data to say how -- about the degradation of the Prolift® as seen in the electron microscopy. I know from the records, from the documents, that there have been these investigations, but I did not have the opportunity to have a look to this. And, therefore, I'm not able to estimate what may be the amount of particles that can be separated or can be released by this degradation process. But considering all of the literature and all my knowledge, I cannot imagine any beneficial effect of it.

Q. But at this time, you're not aware of there being any particles coming from the polypropylene mesh that leads to this inflammatory response, this heightened inflammatory response; is that correct?

I can restate the question. I know it's loud.

Doctor, are there any clinical

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studies or preclinical that show particles coming from the Prolift® mesh as a result of degradation leading to increased inflammation?

A. There are many, many limitations that makes it impossible to create a causal chain between degradation particle loss and inflammation. But taken all together, the increase of surface of a foreign body reaction in a given area of the tissue has to be considered as a risk and not as a beneficial aspect.

Q. And as we said earlier, there's no clinical data that the Prolift® mesh surface increases; is that correct?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I can just repeat my last sentence. There is no clinical data that is -- which is able to demonstrate a causal chain between one certain point and the other.

BY MR. BROWN:

Q. Doctor, are there -- strike that for a second.

Dr. Mang, when he tested the Prolift® mesh, did he use some kind of device to see what kind of particles would come off the Prolift®?

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A. Again, Dr. Muhl?

MR. ANDERSON: Dr. Muhl.

THE WITNESS: Dr. Muhl.

BY MR. BROWN:

Q. Dr. Mung.

A. You are talking about the study of Dr. Mung?

Q. Yes.

A. So please again with --

Q. Yes.

Did Dr. Mung use a utensil or device to see if particles would come off the Prolift® out of the package?

A. We have been sitting together and writing a protocol to see or to separate several steps which may be interesting to know whether this creates some particles or which eases the release of some particles. And there we defined several time periods to look after these time periods and put all this together in an experimental setting. So we can go to -- through this experimental setting and to the data in detail, but then we should do it with the paper.

Q. Well, I'm speaking more on the -- you reviewed the expert report of Dr. Mung; is that

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right?
A. Yeah.
Q. And Dr. Mung's expert report -- have you reviewed Dr. Mung's expert report?
A. I've read it.
Q. And did Dr. Mung use a device to make contact with the Prolift® to see if particles would come off the Prolift®?
MR. ANDERSON: He just said he'd like to see it.
BY MR. BROWN:
Q. Do you know if he did that or not?
MR. ANDERSON: Again, he said he'd like to see it.
THE WITNESS: Yeah, we have to go to the paperwork. I know that it was very -- many different steps to look whether there was one or to objectify whether there was a particle loss or not. So many details, then we should go line by line in the protocol and then we can see it.
BY MR. BROWN:
Q. Doctor, I'm just asking you what you remember as you sit here today.
And so do you remember particles coming from Dr. Mung's test?

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MR. ANDERSON: Again, I think in fairness --
MR. BROWN: Ben, I know what you're asking, but I'm asking him what he knows.
MR. ANDERSON: Well, it's in fairness to him, you should provide it to him.
MR. BROWN: If you want to make it across the litigation that every time we ask a question, that we have to show the document --
MR. ANDERSON: If he asked to see it?
MR. BROWN: -- we'll be glad to do so. You can ask your counterpart about that.
THE WITNESS: As I remember correctly, it's some time ago, then some was just to look what has been collected in the package, and some has been by some instrument to look what can be released by some gentle forces there. And then he looked what can be released by some, additionally, I think hydrosonic has been applied there, and then what is done by some cutting of 1 or 2 centimeters. It just -- yeah.
BY MR. BROWN:
Q. And are you aware of any clinical or preclinical studies that show where any particles that come off as the Prolift® is being placed in the

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pelvic floor leads to complications?
A. I'm aware of many, many preclinical studies showing that increased surface is associated with increased inflammation of the tissue around, but I've -- I'm not aware of a specific investigation looking for the Prolift® and the amount of particles around there. Yeah.
Q. Doctor, do other meshes shed these particles?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: We did not make a systematic analysis of all meshes available, about the quantity of particulate release after -- before trimming and after trimming. I know from my experience that the Marlex® mesh was an extreme bad example of releasing a lot of these particles, that it was not so evidence for the clinician during the OR for the Vypro® and for the Ultrapro®. It is not like this.
I know from the literature studies about slings that there are differences in between the various structures. So, yeah, there -- it depends from the textile structure mainly the degree of particle release.

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BY MR. BROWN:
Q. What meshes have you tested to see what kind of particles come from that mesh?
A. We can look to the report which meshes are there.
MR. ANDERSON: Did you say which he studied or which have been studied? I missed that, I'm sorry.
MR. BROWN: What Dr. Klinge has studied, which ones he has studied.
THE WITNESS: So this report is on Prolift® and Prolift+M®.
BY MR. BROWN:
Q. Doctor, do you know if there's ever been any studies on whether PVDF sheds particles?
A. I'm not sure, because I did not realize or remember directly the figures, how much particle loss has to be considered with a DynaMesh structure there.
Q. Doctor, if you look at page 43 of your report, it actually starts 42.
If you look on page 43, Doctor?
A. I'm looking.
Q. It's the first paragraph, the third sentence where it says "Furthermore."

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A. Second -- third, "Furthermore this study clearly shows."
Q. Doctor, when you state, "contamination has to be considered as a rule when using meshes in the pelvic floor," why do you state that?
A. I've learned from the beginning of my surgical career that the presence of bacteria in combination with a foreign body is a concern and that you should avoid it and that you should be very careful not to use foreign bodies in the presence of bacteria, despite -- and that you should use prophylactic antibiotics even in clean wounds if you are placing an -- a foreign body. And still today, there is a controversial discussion whether it's justified to use or to implant a mesh in the abdominal cavity after damage of thin bowels and thick bowels.
The general opinion is that in cases of severe contamination, that means already the damage of the thick bowel, where you have a lot of bacteria, that you should stop to use a textile implant at the same operation, but you have to wait for it.
So our experience, my experience and

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I would say the experience of the surgical community, is to be very, very resistant or very limited use of foreign body materials in combination with some contamination in that field. That is what I've taught, what I can say for abdominal surgery. And --
Q. Doctor, you know my question was limited to pelvic floor, though.
A. At the beginning, I was really surprised about the use of pelvic floor meshes by this approach. And this concern is confirmed by this study where they looked to the bacterial contamination of these meshes. And, therefore, I hope I write it correctly, that in contrast to the use of meshes in the abdominal wall, contamination is to be considered as a rule. This is a much higher risk than I would assume for the abdominal wall, for the implantation in the abdominal wall. The contamination with bacteria is a more important concern than in the abdominal wall.
Q. What causes the increased contamination in the pelvic floor, Doctor?
A. To my knowledge, it is the access. We have similar experiences in our sort of surgery that we even -- if you compare laparoscopic and open

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access, then you can decrease the incidence of infections with the laparoscopic access in comparison to the open one, and to make a transvaginal approach, bias the risk for bacterial contamination if you use a mesh.
Q. Are you saying abscess or what --
MR. ANDERSON: Access, access.
THE WITNESS: The access or the approach.
MR. ANDERSON: To access.
BY MR. BROWN:
Q. So why does the access in the pelvic floor lead to higher contamination, in your opinion?
MR. ANDERSON: Asked and answered.
Go ahead.
BY MR. BROWN:
Q. What about accessing through the pelvic floor leads to higher contamination for the mesh?
A. No. The transvaginal approach to place the mesh means that you have a risk for carrying bacterias into the wound. And this is confirmed by the studies looking to bacteria at the mesh surface.
Q. Do you have a risk of having bacteria

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when you place it in -- or place the mesh in abdominally as well?
A. You always have a risk with a foreign body, but you have to reduce it at maximum. And for abdominal wall, it is reduced, first of all, by getting or optimizing the indication. Second, by optimizing the access --
MR. ANDERSON: The access.
THE WITNESS: -- the way to bring it in. And these are the options to do so.
BY MR. BROWN:
Q. Doctor, would you agree that the mesh construction for Prolift® has sufficient -- scratch that.
Would you agree that the mesh -- scratch that one more time.
Would you agree that the Prolift® as it's constructed has sufficiently large pores to allow the body to clean out bacteria that might become on it?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: No, I think it is not sufficient pore size to clean out, not because of the reason that it is impossible for macrophages to

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reach these bacterias, but we know from many of our studies that the function of the macrophages is impaired in the neighborhood of foreign bodies if there is a present bacterial infection. So the defense capability of the macrophages cleaning, what you say cleaning the body from the bacteria, is reduced, and that is -- that makes the tremendous risk. If you have an infected foreign body, if you have an infected mesh, everyone knows that it is hard to get control of this infection, if there are only some risks of this mesh remain in the tissue. So cleaning of an infection, though I know some report that they can treat a mesh infection just by waiting, very many reports confirmed that it is very difficult to get control of a mesh infection.

BY MR. BROWN:

Q. Is that a Prolift® mesh, Doctor?

A. That is -- there are reports about severe mesh infections for the Prolift®, but for all other meshes as well. It is a general experience for all -- I would say for all surgical fields, that the control of an infection in the presence of a foreign body requires the removal of the foreign body.

Q. So, Doctor, it's your testimony that

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the Prolift® is constructed in such a way that when bacteria gets on it, it usually needs to be removed?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: For most of the clinical experience, it is necessary to remove. But, however, it depends from the presence of this infection whether it is surrounded by bacterial liquid or whether it's just a short edge which may be not covered any longer by some tissues. So, of course, because of our difficulties to remove a mesh, and in particularly to remove the Prolift®, therefore, we usually try to make a conservative treatment to heal it out. But very often, it does not work.

BY MR. BROWN:

Q. Doctor, what are the infection rates for the Prolift®?

A. There are figures, if I remember correctly, but we can go to the FDA report or to look there. But if I am -- remember correctly, it's about maybe 3 to 5 percent in some infection, but it is difficult to separate this from erosion, local, which is a local infection as well. And the critical point is that you have to wait a long time

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to summarize or to come to a final point where this -- how often this infection occurs.

If we just look to the subgroup of meshes that has been explanted because of infection from Professor Klosterhalfen, the median interval of explantation is two years. And if I remember correctly, there has been a huge study from the US veteran hospitals, I guess about more than 1,000 mesh operations for incisional hernia. And they reported similarly that it is a delay of two years. So you have to consider that there is a lifelong risk for manifestation of infection. And, therefore, it is hard for me to say what is the incidence of it, at what time point.

Q. Doctor, are you familiar with the Cosson study where he did a three-year study and found less than 1 percent of infection?

A. Am I -- yeah, I remember.

Q. If mesh contamination is the rule, how do you explain infection rates of around even 1, 2 and 3 percent if the Prolift® is not constructed in such a way where the body can't clean it out?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: The simple reason is

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that we don't have to treat -- we are not treating standardized patients with -- which are healthy. And you add some surgical trauma to it. You have to consider that you have females of different ages, different co-morbidities, that maybe some of them have an impaired immunological defense capacity. So maybe in the very young patients, in the healthy patients, you have a very, very low infection risk; but if you have an additional risk by increased surface, increased number of bacteria, specific strain of bacteria as well, it may occur, and obviously it occurred, that in some patients, there are some infections, there manifests some infections, though in many others, in the period you follow up, you didn't see it. But maybe you just have to wait.

BY MR. BROWN:

Q. Doctor, is it your testimony that contamination is the rule for meshes placed through the vagina and that the Prolift® doesn't allow itself to be cleared out with infection and only has infection rates of 1, 2 and 3 percent?

MR. ANDERSON: Objection to form.

THE WITNESS: It's a chain of different -- of various statements there in your

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sentence.
BY MR. BROWN:
Q. Do you want me to restate it, Doctor?
Here's what I want to know.
Is it your testimony that if contamination is the rule and the Prolift® cannot clean out --
A. First part, can we do it in parts?
Q. Let me ask you this.
Is contamination the rule when placing a mesh in pelvic floor repair?
A. A rule if you mean 100 percent, that I'm not sure to do so.
Q. Most of the time?
A. But as the studies indicate that it is a considerable risk, which is different to other fields of surgery. So there is a specific risk because of this contamination in -- which has to be considered, yes.
Q. Doctor, if contamination is the rule and the Prolift® mesh doesn't allow itself to be cleared out from the body, what kind of infection rates would you expect to see?
MR. ANDERSON: Objection.
Go ahead.

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THE WITNESS: I don't know any mesh that is able to clear themself by some bacteria.
BY MR. BROWN:
Q. Allow the mesh to clear itself?
MR. ANDERSON: Same objection.
BY MR. BROWN:
Q. Allow the body to clear the infection if the infection is on the mesh?
MR. ANDERSON: Same objection.
BY MR. BROWN:
Q. Let me restate it so I have got one question out there, and then you can answer it.
If contamination for mesh put in pelvic floor is the rule, what would you expect the infection rate to be for the Prolift® mesh when it's constructed in such a way that it does not allow the body to clear it out, the infection?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I do not expect, or I know that it is not -- contamination of one bacteria of a surface usually is not enough to create an infection, but the persistence of these or the number of bacterias that get attached to this, the surface, the type of bacterias there, they will

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increase the risk for a specific -- for a population of patients for making or for getting an infection. And I believe that an optimum procedure and an optimum device will have no infection.
BY MR. BROWN:
Q. What is an optimum device that prevents infection?
A. We told already or we talked about already that it's difficult to find the best device. But from the point of the view of a patient and from the point of the view of a surgeon, I want to have a device which, even with the risk of contamination, does not lead to a single infection there, because the risk of any revision is considerable.
Q. And is there any device, Doctor, on the market today that prevents any infection?
MR. ANDERSON: Any mesh device?
MR. BROWN: Any mesh device.
THE WITNESS: Which prevents -- it's a difficult topic whether there is some which prevents it. But the history is clear, there has been removed some of the devices because of the problem for infection. There has been some devices that has been used in the pelvic floor that have been removed, mainly, so far I remember, because of

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infection. And, therefore, we are sure and we know that this risk for manifest infection is influenced by the quality of the structure of the device. Yes.
BY MR. BROWN:
Q. My question is, is there a device, a mesh device, that's out there today that prevents infection?
A. Obviously there are meshes or structures that are better than others.
Q. But are there any that there's no infection as a result of that mesh?
A. You cannot answer this, because infection may have several different reasons, and only -- and some parts of it are affected by the structures but not all.
Q. Can you --
A. There are infections even without any mesh material. And, of course, this cannot be affected by the best material if it's not used.
Q. Can you point to a mesh today for pelvic floor repair or hernia repair that has no risk of infection?
A. There is no procedure in medicine in general, in all fields, that has no risk for infection.

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Q. Doctor, what mesh construction do you believe is out there today that is better than the Prolift® to prevent infection?
A. Maybe Prolift+M®, because it has a reduced surface. But I'm -- as I said, there is -- to my knowledge, there is no competitive study to show in clinical trials that one is superior to the other in regard to the infection. And it is very difficult to make these clinical trials and to look to it, because you have to wait for 10, 15 years.
However, all the preclinical studies we did, they clearly indicate, and I have no doubts to this, that the risk for infection is affected by the surface size and the degree of the contamination and the type of the germs that are attached to the surface. And this has to be investigated, and the amount of surface has to be really reduced, and then you can expect that you have a lowered risk, not a nonpercent risk, but a lowered risk.
Q. Doctor, are there any studies that you can point to that the Prolift+M® has a lower infection rate than the Prolift®?
A. That Prolift+M® has a lower infection rate, the clinical studies, studies comparing this.
I did not get an information on a

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study that is doing in regards to specify this.
Q. So there's nothing you can point to that shows that there is another mesh construction that has a lower infection rate than the Prolift®; is that correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I fear this topic has not been investigated when having access to the -- which of the two materials is better than the other.
BY MR. BROWN:
Q. Doctor, we'll come back to my question then, which is --
MR. BROWN: Would you read it back, Ann Marie?
- - -
(The court reporter read the pertinent part of the record.)
- - -
MR. ANDERSON: Objection, asked and answered.
THE WITNESS: There is a lack of knowledge, yeah.
MR. BROWN: Would you read back my question? I'm asking you, can you point to a study,

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but go ahead and read back my question.
- - -
(The court reporter read the pertinent part of the record.)
- - -
MR. ANDERSON: Same objection, asked and answered.
Go ahead.
THE WITNESS: No, I do not have a -- I did not find in the literature a study which addresses the differences in the attachment of bacteria to the different surface and whether the reduced surface of the Prolift+M® is related to a reduced attachment of bacteria and later on will have a reduced infection rate.
BY MR. BROWN:
Q. Doctor, what does it mean to you to potentiate infection with regard to a mesh?
A. It means that the clinical manifestation of an infection is accelerated and intensified in the presence of a foreign body. This is -- yeah. This is current knowledge in surgery as well, and there are a lot of experimental data showing what happens if you add bacteria to the wound of a alloplastic material.

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Q. Have you seen any studies, Doctor, where bacteria has been added to the mesh in Prolift® to see if it potentiates infection or it does not potentiate infection?
A. Surprisingly, I did not remember -- or in the moment, I did not remember any study where the aim was to control the bacterial adherence of various germs to the surface of the Prolift®.
Q. Doctor, let me just ask you if you -- I'm showing you Exhibit 18, which is a study by Thomas or Dr. Barbolt.
- - -
(Deposition Exhibit No. Klinge-18, Article entitled "Biology of polypropylene/polyglactin 910 grafts", was marked for identification.)
- - -
BY MR. BROWN:
Q. It's Exhibit 18.
Doctor, a couple different things were studied here, but we're talking right now just about the infection potentiation. So he discusses a study starting on page S29. Do you see where it says "Infection potentiation"? If you would, Doctor, go ahead and read that section on infection

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potentiation and then I'll ask you a couple questions about it.

Tell me whenever you're through, Doctor.

Have you had a chance to review it?

MR. ANDERSON: Review what? The whole article or you just --

MR. BROWN: No.

MR. ANDERSON: -- want him to look at these few paragraphs?

MR. BROWN: Yeah. I mean, there's a couple of different studies and this is a review of studies, and I'm only asking about the "Infection potentiation" at this point.

MR. ANDERSON: Okay.

THE WITNESS: So I read this chapter, yes.

BY MR. BROWN:

Q. The "Infection potentiation," right here?

A. Yeah, yeah.

Or maybe it is not necessary, because there are so many things, maybe you can come in details with a single to have a look at it.

Q. Doctor, would you agree in this study

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that the Gynemesh® PS was inoculated with some bacteria?

A. That is right.

Q. And, Doctor, have you seen this study before?

A. Yes, I have seen this study. Yeah.

Q. And after they looked at it, it showed that it was neutral for the presence of bacteria.

Do you see that?

A. I see this, but --

Q. And does that mean that there was no additional bacteria that was originally placed on the mesh?

A. Now, what was -- what my interpretation of this document is, that it -- first of all, he clearly explains what I said is potentiate. He said that you need fewer bacteria. It is well known that in the presence of a firm implant, it takes fewer bacterias to cause infection at the surgical site, infection. So I think I'm in agreement with his position.

Then he took three different meshes. Interestingly, these are different materials than in the studies before. However, he compared some

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biologicals, and we can let them outside, because this is not our job. Then we have the Gynemesh® PS and the Marlex® mesh that he looked at it. He placed staphylococcus aureus. Staphylococcus aureus is not the main germ that has to be considered in the use in the pelvic floor area.

Q. What is that main germ?

A. What?

Q. What is the main germ for the pelvic floor area?

A. It is some gram negative bacteria as well, a lot of it. We can have a look to this study where they made the culture of the germs that were isolated from the mesh. But only staphylococcus aureus, that's mainly sitting on the skin.

We have made own investigations, and we compared different strains of staphylococcus, different strains of E. coli, and saw that it is very different between the different strains of bacteria how they adhere to the surface of this material.

So to really want -- if you want to control the risk for infection by your material in the presence of a contamination, I think you have to do it or I'm sure you have to do it with various

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sorts of germs.

Then he looked after four days, and he saw that they are neutral. So it's not less. It is not more, but it is not less. So what you assume, that there is a cleaning of the body after four days, removing all the bacterias in the presence of the foreign body has not happened there.

So these are just some few remarks where the limitations is. And there is a concern. Yeah.

Q. How long would it take to -- or for a body to clear out some infection?

A. If I look at the database of Professor Klosterhalfen with 1,000 explants, I think the latest time point for removal of a device because of infection has been 15 years, if you are looking to --

Q. Doctor, that's not my question at all.

A. What?

Q. So my question is, if there is infection that's on a bacteria --

A. Yeah.

Q. -- how long does it take the body to then clean that infection off?

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MR. ANDERSON: Objection, because he's answering the question.
THE WITNESS: That was my answer. Lifelong risk. You have to consider a lifelong risk. Sometimes it never occur. The bacteria are sitting in the biofilm there, smooth, calm, and then by a sudden breaking down of the immunological defense capability or some germs in the blood, it's reactivated and then you have the manifest infection after three years, five years. And in the time period between, you don't see anything.
BY MR. BROWN:
Q. Isn't that normally, Doctor, when you've got a mesh that's encapsulated for the germs to come through the blood?
A. I didn't get the point.
Q. When you've got a mesh -- didn't you say that years later there can be bacteria that comes through your blood?
A. Yes, yes.
Q. Doesn't that normally occur when the mesh is encapsulated?
A. No, no, no, no. This encapsulation, this fibrotic encapsulation, is not sufficient to prevent any invasion of bacteria. Bacteria, they're

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very small. You have even in the scar a lot of vessels, so you need blood flow. Otherwise, this fibrotic capsule will get necrotic there. So no way to prevent this.
And if you look to one other field in medicine, or if you have cardiac valves, you are asked to get an antibiotic prophylaxis lifelong to prevent this secondary attachment of bacteria. So our experience is that, despite it may be a low risk, whatever low is, but it's a lifelong risk. And this cannot be contraindicated or it is not sufficient to have this standard mouse model in this setting to exclude this risk.
Q. Would you agree it's a low risk for infection with the Prolift®?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I think we cannot agree what is low and what is not low, because this is a difficult question. Even if you have a low risk to die at a very cosmetic operation, this is not acceptable, so, yeah. Low in relation to what? So I will not answer it that it is low.
BY MR. BROWN:
Q. Doctor, you used the word "low" and

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said that there was a low infection rate or a low infection.
And so I'm asking you what do you mean by that, when you say a low infection?
A. Yeah. I forgot the question mark, to say that this is a phrase just to give you some indication that it's not 100 percent.
MR. ANDERSON: You say question mark. Did you mean quotation mark?
THE WITNESS: Quotation mark, yeah. So I forgot the quotation mark. And to indicate that it doesn't make any sense to ask me for a definite number to this. But sorry.
BY MR. BROWN:
Q. Doctor, do you have any studies that you can point to that the Prolift® potentiates infection?
A. I know that there is a considerable risk for infection that this happens. I cannot even imagine, or I don't understand how to potentiate it, what does it mean. I think it is a fact that, in the presence, if you implant a medical device, an alloplastic material, in the form from the Prolift® in this contaminated field, in this contaminated area, that you have to take into account that in

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some patients, there will be an infection complication there. That is a fact. Whether this Prolift® potentiated or linearly increased the risk, or in what other conditions it may affect the risk and what is the relevance in regards to the other issues, I'm not able to separate this.
Q. Doctor, are you saying that you do not understand what the terminology means "potentiate infection," or do you understand that?
MR. ANDERSON: Objection.
THE WITNESS: It has to be put in the context.
BY MR. BROWN:
Q. So just by me asking you what is potentiation of infection, you would say, I can't answer that?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: No. If you mean it increase the risk for infection, that I can agree to this.
BY MR. BROWN:
Q. Let me put it --
MR. ANDERSON: You can or can't?
THE WITNESS: I can agree to this.

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BY MR. BROWN:
Q. Let me put it in context.
Can you point to any studies that show that the Prolift® mesh potentiates infection?
MR. ANDERSON: Objection for the same reasons stated.
Go ahead.
THE WITNESS: No, I do not have the data showing -- confirming in an experimental setting that Prolift® is -- what were the term?
BY MR. BROWN:
Q. Potentiates infection.
A. Potentiates infections as a specific topic for investigation.
Q. Doctor, let me ask you this. This is on page S29 of this study.
If you look up at the top right, that Figure 4, are you able to look at that picture and tell if that is a low inflammatory response or a high inflammatory response?
A. No. What I see if I look to the Figure 4, and comparing it to the Figure 2, then my impression is that the inflammatory activity of Figure 4, the Gynemesh® PS, is less than in Figure 2.

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And, second, I see this -- these collagen bridging between all fibers in Figure 4. So this is a proof that the Gynemesh® PS has a lower inflammatory activity in comparison to the Marlex® mesh, but it is a proof as well that you see this fibrotic linkage, this bridging, in the Gynemesh® PS at 91 days.
Q. Doctor --
A. In this location.
Q. So, Doctor, in your opinion, from Figure 4, is this what you consider bridging fibrosis?
A. This is -- this reflects bridging fibrosis on the microscopical level.
Q. And does this also characterize encapsulation?
A. No. This is -- so you have to consider different levels. Encapsulation can be seen on the microscopical, there is an encapsulation that can be seen on the microscopical level that you see during the OR only fibrotic tissue, but as well you can define it as, on the microscopical level, where you have all these same bundles of collagen at the surface around all of these meshes, but it's not necessarily seen macroscopically.

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Q. Doctor, is this picture, Figure 4, does this show any fatty tissue ingrowth?
A. That is my concern, no. Definitely I don't see that the pores are filled with the local fatty tissue there. But I see this bridging. And if you compare the distance of the filaments, you see that the distance is not very much. So from this slide, you get the impression that the pores are not very large, not sufficiently large enough to allow the ingrowth of fatty tissue.
Q. Make sure I'm hearing you right.
So on Figure 4, this bridging fibrosis would prevent fatty tissue ingrowth.
Is that what you're saying?
A. Usually -- yes. When there is sometimes a scar, there is no possibility to remove this scar by the body, unfortunately.
- - -
(Deposition Exhibit No. Klinge-19, PowerPoint entitled "Tissue Reaction and Integration of Polypropylene-Based Surgical Mesh in Rats," Bates stamped ETH.MESH.02319001, was marked for identification.)
- - -

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BY MR. BROWN:
Q. Doctor, if you would go to the last page of -- I'm handing you Exhibit 19. And on Exhibit 19 is a PowerPoint slide dealing with mesh in rats.
Doctor, if you look at the very last page -- you have it in front of you.
Doctor, does that show to you encapsulation?
A. What I see is that it is excised tissue, and I see this -- a mesh there placed on it. And this mesh is -- seems to be covered by a thin layer of cell. And I would expect that this is a mesh that has been removed from the abdominal wall cavity. Or it is -- it has formed a -- some sort of cystic environment there. But I do not see a real tissue integration from this side, only from the other side. Of course, macroscopically, I do not see any encapsulation there, fibrotic encapsulation in this field. Whether it is -- how it looks in the microscopical level, you have to look to this as it is quite similar to the other staining. I note -- this indicates that the microscopical image we just recently saw, it shows this bridging on the microscopical level, and, therefore, I have no doubt

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that there was this bridging there.
But if I look to this image, I cannot -- or I cannot understand that this mesh material was removed from a subcutaneous space there. When I extract the meshes from the subcutaneous space, I've never seen this smooth, shiny layer covering the mesh. That is not typical. And, therefore, I would like to see the samples there. Because if there are other studies making this IPOM mesh, placing it on the abdominal cavity from inside, and there you see as well this very thin layer of mesothelial cells and then you have this shiny appearance. But if you make just an extraction from the subcutaneous space where the mesh is attached to the fascia and to the surrounding fat tissue, it hardly look like this.
So I need an explanation what happens in this field, where it really comes from, and then it may be possible to explain this. But if there were certain conditions that are not typical, I think it is very difficult to find an interpretation or to make a good interpretation of what happens in this figure. I'm not able to do so.
Q. Okay. Let me ask you --
A. Because for the abdominal careful, it

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is quite usual to see it like this, but not in the subcutaneous space. Sorry.
- - -
(Deposition Exhibit No. Klinge-20, Article entitled "The Argument for Lightweight Polypropylene Mesh in Hernia Repair", was marked for identification.)
- - -
BY MR. BROWN:
Q. Doctor, I'm showing you Exhibit 20, which is a study by Dr. Cobb in 2005.
Doctor, if you'll turn to page 65.
Doctor, do you see where it says, "To answer this question" on the far right column?
A. Yes.
Q. Okay. Dr. Cobb and his team sought to assess the pressures of the intraabdomen by putting a bladder catheter.
Do you believe that's an appropriate way of testing the pelvic pressures?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: It is an appropriate way to measure the intraabdominal pressure.
BY MR. BROWN:

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Q. It's an appropriate way?
A. To measure the intraabdominal pressure.
Q. Would the intraabdominal pressure, in your opinion, include the pelvic floor?
A. It gives some estimate for the pressures that may stress the pelvic tissue as well.
Q. Doctor, isn't the bladder in the pelvic floor?
A. Hmm?
Q. Isn't the bladder in the pelvic floor?
A. No. It is on top of the pelvic floor.
Q. Okay. And the pressures coming from the pelvic floor would come to the bladder.
Do you agree with that?
MR. ANDERSON: Objection.
THE WITNESS: The pelvic floor is a compound of muscle and ligaments and fascia and nerves and vessels. I don't understand why -- where the pressure is originated.
BY MR. BROWN:
Q. You're saying you don't know where the pressure originates from the pelvic floor?

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A. You have asked me whether the pressure from the pelvic floor is transferred to the bladder. So this is a setting where you measure the pressure as newton per square centimeters within the abdominal cavity. Of course you have a -- it is one space to go down to almost the pelvic floor. It stops a little bit above. You have other slightly different or you have different values if you are measuring in the stomach, in the free abdominal cavity or in the bladder. So you always have variances in your measurements there.
Q. Doctor, if you wanted to measure the pelvic floor forces, where would you measure them?
MR. ANDERSON: Did you say forces?
MR. BROWN: Yes.
MR. ANDERSON: Okay.
THE WITNESS: Where would I measure the forces? There is no perfect way to come to a precise measurement of the forces, the pressures and so on in the moment. So you have to think of several models, all with the limitations and all with specific -- covering specific aspects there in this field. The point is that measuring the pressure usually includes that you need some knowledge about the area. Otherwise, you will not

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have a pressure. Usually you don't know the area or the thickness of a layer, and, therefore, usually it does not help if you are measuring pressures if you want to transfer it to some anatomical structures or to some textiles. That is a difference. That is a difficulty.

If you want to measure forces, you can try to measure the retaining forces of tissues by just -- by placing some sutures and look how -- what are the forces they withstand and to removal of these things. You can extract -- as Cosson did extensively, you can take some of these tissues, cut them in stripes and make some uniaxial measurements. You can do some excision of the tissue and make some test pressing through the stamp as well for these tissues. However, all of this together just gives you a rough estimate of the biomechanical reality there.

BY MR. BROWN:

Q. Have you tested, Doctor, the pelvic floor forces?

A. We have in -- we have tested -- we have measured personally not the forces, but we have tested the capability of the tissue to withstand extraction, because we made -- and this is

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published, I think. We made investigations for how to anchor -- how to place anchor, what is the holding capacity of anchors in the tissue. And this has been done with focus on the pelvic floor in pigs.

Q. But, Doctor, is the answer to my question no, that you have not studied the pelvic floor forces in a human?

A. We have not made investigations, yeah, with this focus.

Q. If you look at Dr. Cobb, he has a range of 64 millimeters of mercury to 252 millimeters of mercury.

Do you have any reason to dispute that those are similar pressures in the pelvic floor?

A. I know that this publication appears after ours. And in the development of the Vypro®, we assumed a maximum pressure I think is 150 millimeters Hg, and so later on he even exceeded it a little bit. But I have no doubts that this is -- can be considered as a maximum intraabdominal pressure. This is the range. It is in the humans, in the abdominal cavity. I would not expect a value which is higher.

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Q. Now, Doctor, if you look it says that this was performed on fit patients or healthy patients.

Do you see that?

A. Yes.

Q. Doctor, do you agree that there would be an increased pressure on an obese patient?

MR. ANDERSON: Objection.

BY MR. BROWN:

Q. Than a healthy patient?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I know some obese patients where they surely will not have an increased intraabdominal pressure because they are -- their capability of muscle activity is quite restricted. So adipose is not sufficient to predict an increased abdominal wall -- intraabdominal pressure.

BY MR. BROWN:

Q. Are you saying, Doctor, it's not possible for an obese patient to have a higher pressure?

A. No. I don't want to say this general statement that generally obese cannot be. I know,

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if you ask me if an obese in general has an increased intraabdominal pressure, I say that is not true, because I personally have in front of my eyes some obese patients where I think or I'm sure that they will not have this peak pressure as a 20 years old healthy bodybuilder which is lifting 300 pounds.

Q. Doctor, would an obese patient have a higher pressure in the pelvic floor than a healthy patient in the pelvic floor?

A. I don't see that there is a way to make the difference. If you measure the pressure just above the pelvic floor and in the abdominal cavity, it is one space, so you shouldn't expect some differences there.

Q. And is that an assumption you're making, Doctor? Do you have any studies that support what you just said?

A. It is, as it was written in some -- in the reports, it's just physics.

Q. Doctor, is it also possible that patients could do more strenuous activities than jumping that would lead to higher forces in the pelvic floor?

A. In the moment, we are -- if you refer to this article, we are not talking about forces.

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We are talking about pressures. And these pressures may differ. And jumping, I can do a jumping without using my muscle as well, so I would not expect that the intraabdominal pressure will increase. If you have some other activities, maybe you have a maximum peak level of intraabdominal pressure. And I would agree that if designing a textile to reinforce these tissues, you have to consider that you have to cover these peak pressures as well, of course.

Q. Doctor --

A. Or you have -- sorry.

Or if this is not possible to do it in one device, you have to provide two devices, one for the heavy worker and one for the others, if you can realize it only in this way to lower the specific risk.

Q. And, Doctor, what I believe you stated earlier is that the Prolift® mesh is overengineered; is that correct?

A. From all my data I saw, I have the impression that the Prolift® is overengineered.

Q. And, Doctor, what is the optimal strength for a mesh in the pelvic floor?

A. I have no indication from all the literature, from all our experiences, from all our

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measurements from tissue that there has to be considered a tensile strength of more than the 16 newton per centimeters that we estimate for the abdominal wall. There is some indication that it's even lower, but it depends from the way you use it which structure you want to reinforce whether you have additional tissue that contributes to the stability or -- yeah. At least these are some aspects that you have to consider.

Q. So you're saying that an optimal strength would be 16 per newton centimeters in the pelvic floor?

A. No. I said that it is -- I have no arguments to say that it is more. I do not have the possibility to say that the optimum is in the moment.

Q. And, Doctor, what complications have occurred as a result of Prolift® having the strength that it has instead of the 16 newton per centimeters or below?

A. The overengineering leads to a unnecessary plus of material, and it is followed by pores that are smaller than necessary. It leads to a plus of surface. So overall, this overengineering is followed by a more intense local inflammatory

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reaction of the tissues, a more intense formation of scar tissue. And this is related to more shrinkage, more erosion, more infections, more pain, all these clinical side effects that happened if you have a textile implant. And this is integrated only in -- or mainly in scar. This is the consequence of an overengineering, that it is possible to reduce all of this. The first evidence is the Prolift+M®, where the material is reduced. For example, it has --

Q. I'm glad you mentioned Prolift+M®, because I was going to do the same thing.

Have you seen, Doctor, studies comparing Prolift® and Prolift+M® specifically with erosion rates?

A. With what?

Q. Have you seen studies with Prolift® and with Prolift+M® and seen where the Prolift+M® erosion rate is below the Prolift® erosion rate, any kind of significant difference, have you seen that?

A. In the moment, I will not -- I do not remember that there is a specific study comparing these two different materials. However, I wouldn't expect it, because the Prolift+M®, based on Ultrapro®, has some other disadvantages. It has a

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lower surface. It is a reduced amount of material. It has some beneficial parts in this regard, but it has some other disadvantages. And I would expect that this compensates any beneficial effect on the complication rates.

So after all, as maybe with the Vypro®, you have some advantages in some regard, but overall, the rate of clinical complications in the patients, I'm worried about it, but maybe not been decreased by this.

Q. Doctor, you're aware that there are three-year studies for Prolift®, there are three-year studies for Prolift+M®.

And you are aware that there have not been significant decreases in erosion rates for Prolift+M®?

A. Yeah, there is. And my explanation is that you have some problem or that there is -- there are some problems in the structure from the Prolift+M® that can explain why there is this problem.

Q. What is it about the Prolift+M® structure that leads to erosions?

A. The Ultrapro® or Prolift+M®, which is a similar thing, it has a very -- it has larger

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pores. It has a reduced amount of polypropylene. However, I've not seen, despite these three years of experience, that there has been any mechanical problem due to this reduced amount of polypropylene. So, therefore, this is my strongest indication that the Prolift®, per se, is overengineered in comparison to this, because Prolift+M® does not have any significant problems in this regard.

So Prolift+M®, the Ultrapro®, has bigger pores, so the area of -- where I expect bridging is lower, but only in the -- at rest. If you put only the slightest strain to it, the Ultrapro® which is very, very anisotropic, it is the prototype of an anisotropic mesh, I don't know any other that is a mesh like this. So in a certain direction, these collapse -- or these pores collapse with the Ultrapro® at very, very low strain. So then you lost all advantages of the large pores, and you get a very small porous mesh, if there is only some sort of strain to this material. In comparison, the Prolift® in this regard is better, because it withstands a little bit better these forces.

There is another disadvantage of the Ultrapro®, but I think this is mainly important for

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the incisional hernia, that is that you have a very low connection of the filaments to each other so that it is separating quite easy if you have strain in a certain direction. But it may be -- in some patients, it may be a concern in the arms, because you -- because of the heterogeneity of the course of the fibers, it is not controlled where -- what is the stability at every part of the arms. There should be a variation in the stability within the arms.

Q. Doctor, are you saying that the Ultrapro®, when more stress is placed on it, that the pores get smaller and it's the bridging fibrosis with the Ultrapro® that leads to erosions?

A. This will increase the risk for all these fibrotic reactions, erosions, as well, yes.

Q. Doctor, are there any other reasons why erosions take place in the pelvic floor besides bridging fibrosis?

A. Of course there is an incision. From my surgical standpoint, there was an incision and it was closed. And it depends, from the type of dissection there, of the preparation, how much of dissection is used, from the wound healing capacity of the patient, whether it's compromised or not.

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So, yeah, all this together may -- or surely influences the kind of wound healing in this area. But every contamination of bacteria will impair the wound healing capacity in this field. So all these risk factors together will define the risk in a patient.

Q. Doctor, what mesh construction are you aware of that leads to lower erosion rates than the Prolift®?

A. Do you know -- you asked me, do you know, sorry, or do you expect?

Q. No. Do you know?

A. Do you know?

Q. Yes.

A. In the moment, there is only the knowledge of this risk, but I'm not aware of any direct clinical comparisons, comparative studies in this regard.

Q. What other mesh construction are you aware of, Doctor, that causes less chronic pain in the pelvic floor than the Prolift®?

MR. ANDERSON: Objection.

THE WITNESS: I do not know any other mesh construction that is used for the Prolift® procedure.

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BY MR. BROWN:

Q. Doctor, let me ask you one thing on page 19 of your report.

At the bottom where it says, "However, as Cosson."

Doctor, why if there is a vaginal tissue rupture strain of about 20 newtons per centimeter, why would you want a mesh that is in the range of 2 to 10 newtons per centimeter?

A. This paragraph, first of all, stated that the tissue withstand usually, and this is in accordance with our measurements of other tissues as well, that usually at a strain of 20 newton per centimeters, you have cutting through of any holding device from the tissues. So if the tissue is not able to withstand higher forces, I cannot imagine the necessity of any other additional device to withstand higher forces. Therefore, the upper limit of the tissue is 20 newton. Our estimate dealing with the intraabdominal pressure and the circumference of the abdominal wall cavity comes up to the end of 16 newton. This depends from the radius.

So if you're going down in the pelvic and you have a smaller radius than in the abdominal

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wall cavity, I think it is reasonable to go lower. And this is what my colleagues told me that during the operation, they have the feeling, they have the feeling that the forces they apply there are quite low. But, however, more precise measurements or estimations are still lacking. Point.

MR. BROWN: Doctor, let me know kind of how you're doing. We want to get you out of here by right around 5:00, but do you want to take a five- to ten-minute break or do you want to push?

MR. ANDERSON: Let's take five to ten and then we'll keep pushing.

- - -

(A recess was taken from 4:18 p.m. to 4:31 p.m.)

- - -

BY MR. BROWN:

Q. Doctor, can you define for me elasticity, what that means?

Let me restate that. Strike that question.

The elasticity for mesh, what does that mean?

A. If you want to know the complexity of this term, I think a good reference is the report of

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Professor Williams. He used different terms to describe this, the e (module of elasticity), stretchability, flexibility and all these things. I think, if I remember in the '90s, when I looked to the textile properties of meshes, they usually give the -- what they called elasticity at the point of rupture of the mesh. That is the -- an extreme stretchability or stretching of the mesh. And when it ruptured, then they said, this is the elasticity of this mesh.

We rapidly got the idea that this is not relevant to know for a Prolene® mesh, what is the stretching at this maximum strength that is possible there. Therefore, we looked at the stretchability, the deformation of the mesh at more or less physiological values. Therefore, we tried to measure the elongation of a mesh at a strain, for example, of 16 newton per centimeters, because we had the feeling that if you have an elongation of the muscle in the range to a mechanical strain of 16 newtons per centimeters, the mesh should follow this elongation as well.

And, therefore, one of the first -- or at the beginning of the -- when we define the requirements for the Vypro®, we defined it that we

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wanted to have a mesh with a stretchability or the capability for elongation at a strain of 16 newton of 20 to 30 percent. That was how we got closer to this field. And we just measured at our bellies the change there.

And then you can see that, physiologically, you have an elongation of 2 to 30 percent in your circumference. And then we did some anatomical studies at anatomical corpse and got similar values of about elongation at physiological strain of 20 to 30 percent.

That was tested at the beginning with the first devices uniaxial in a setting. Then later on we wanted to have this elongation at this strain at a -- when testing pressing through the stamp. Then we, again, looked what is the elongation, the deformation of the mesh at a certain strain in this one.

So that -- this was used -- has been used to define the capability for elongation of the textile structures to identify which textile structures is better than the other, the uniaxial testing and then testing through the stem.

Later on --

Q. Doctor, you do know that I just asked

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you, how do you define elasticity?

A. Yes. All this together.

Q. Okay.

MR. ANDERSON: It is a complicated question.

THE WITNESS: So it's not finished.

BY MR. BROWN:

Q. Go ahead.

A. Elasticity -- please, one important thing is elasticity of a mesh is not the elasticity -- or you have to separate the elasticity of the filament, of the fibers. There is usually very limited elasticity of the single fibers. There is some additional stretchability, capability for elongation by the textile, by the course of the fibers. If there is some space left there, then when you have this stretching, then it can be that you gain some lengths and that you get some what may be called elasticity, but, of course, is elongation of the mesh.

And the third point, and this is the most important thing, is that most of the length that you get by mechanical stressing the mesh is done by deformation of the pores. This is not the elasticity of the polymer or the structure, but it

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is -- it depends from the structure of the textile. Therefore, is it so difficult, and the other point Professor Williams mentioned as well, was the flexibility of the mesh, that eases the handling during the operation, that has to be considered as well.

Q. We're going to talk about flexibility in just a second.

But as far as the elasticity, does elasticity mean that you can stretch the mesh out and then it comes back to its original shape? Is that a simple definition of it?

A. That is the physical definition of elasticity. Elasticity means that you have a stretch there, and then it comes back. Otherwise, it is a plastic deformation. So for meshes, you usually don't have this coming back into the original position.

Q. So if you stretch it and it doesn't come back to its original position, that's plastic deformation; is that right?

A. That is the definition. There is some -- more or less, it is superimposing both effects, but this is the definition of plastic deformation for me.

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Q. And are you saying in the body that when the mesh begins to stretch out, that it doesn't come back to its original shape but that it deforms?

Let me restate that question, because I want to make sure we're talking about Prolift®.

So for Prolift®, are you saying that when it's placed in the pelvic floor, that when forces are placed on it, that it's going to stretch out and then deform?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: The -- I've read in the reports that there are some -- one of them said or assumed that there is a memory effect of the mesh structure always providing an opening of the pores again when releasing the stress.

So as it is only the collapse of the mesh -- of the pore size, it depends from the size and the stiffness of the filaments, and, of course, of the structure whether -- how big the forces are to reopen after release of the tensile stress.

But there is another effect, and we have tested it with a in vitro, where we placed a mesh on a rough ground. And if you tear it and you have it --

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MR. ANDERSON: Tear it?

THE WITNESS: Tear it.

MR. ANDERSON: Or stretch it?

THE WITNESS: Stretch it. If you stretch it, then you have this elongation and then the pores collapse. If you have a rough ground, it is fixed there in this to some extent. So if you release the stretch from this mesh, it will stay there, because it is fixed to the rough ground. If you have a very smooth ground, it may be that it's going back to this. But if you have a rough ground as, for example, if you place it in tissues, it is unlikely that it will recover completely.

And, therefore, this explains very well what you see in the videos where they place the arms there and release the force. Then you don't see this opening again of the arms and laying flat there, but they stayed there wrinkled and folded there.

BY MR. BROWN:

Q. Doctor --

A. So the reopening capacity is very limited.

Q. And are you basing the reopening being limited on the video or are you basing that on

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anything else?

A. I've -- we did -- to test this effect, we did our in vitro experiments. I saw it on the video. It is an explanation why we very often saw this wrinkling in our histological sections, because it explains that you have this doubling of the mesh from the forces of it. Because this is -- yeah. It is a very good explanation of what we see when looking to the mesh explants.

Q. Are those those 1,000 explants that you talked about earlier?

A. (Witness nods head.)

Q. You have to say yes.

A. Yes. Sorry.

Q. Doctor, how much does the mesh need to -- strike that. Let me ask it a different way.

How elastic does the mesh in the pelvic floor need to be?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Yeah. The answer of this question depends from the configuration, the intention, what you want to reinforce. If you want to reinforce a ligament, which physiologically has a very limited stretchability --

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BY MR. BROWN:
Q. Can we just do pelvic organ prolapse? Is that what you're talking about? That way we can confine it down and you can answer the question.
So how much elasticity does the mesh need for Prolift® to support pelvic organ prolapse?
A. The arms -- from my understanding, the use of the arms are to keep the mesh in place and some -- and, thus, may be regarded as some sort of artificial ligament there in this place.
So for this ligaments to have it in place, if you have a stretchability of 20,000 percent, you will not be satisfied. Therefore, for the arms, the stretchability, yeah, should be limited, should be less than for the flat mesh for the central area, which is close to the vagina -- vaginal tissue which has to go with the other tissue around and should not demonstrate a considerable restriction of this elasticity. So different.
Q. Doctor, you had stated with the Vypro® at 16 newtons, it had 20 to 30 percent elasticity, is that what you're saying, I think you're referencing for hernia.
So what are you saying needs to be

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the elasticity in the pelvic floor?
MR. ANDERSON: Objection, asked and answered, but go ahead.
MR. BROWN: Did he give me a percentage?
MR. ANDERSON: You didn't ask for a percentage there either.
BY MR. BROWN:
Q. Doctor, to be very clear then for everybody so we can get you out of here, is there a percentage of elasticity that is necessary with a mesh in the pelvic floor?
A. There are reasonable arguments to estimate that elasticity or stretchability -- you have to define it carefully what you are thinking about, how you are measuring all this, but it is an elasticity in the field of 20 percent for a flat tissue area should have less risk for making complications with the adjacent tissues than when you use a stiffer one.
If you are using -- if you are just focusing on the arms or the replacement with parts of your prosthesis of ligaments, this can be less, should be less than 20 percent.
Q. Okay. Doctor, if you would, if you'd

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go to page 20 of your report.
On "Elasticity," that's the section we're looking at. And I just want to make sure I understand what you have in your report. We're talking about investigations from Cosson and Gabriel indicating elasticity.
Do you see that?
A. Gabriel, yeah, I see it.
Q. Do you see where it says that they indicate an elasticity, it's got a less than 10 percent sign for fascial tissue, and then 15 greater 100 percent for vaginal tissue. I'm just not sure what you mean here.
Can you tell me what you're trying to tell me with that sentence?
A. We have to go to the literature of Cosson and Gabriel, but so far I remember correctly, they measure the elasticity, the stretchability of tissues and of fascia and of native tissue, and there the figures are coming from their publications.
Q. Does that mean -- and I do not want to put words in your mouth. I just want to understand what the sentence means here.
Does it mean that you can have an

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elasticity of less than 10 percent for fascial tissue? Is that what that means?
A. The intention is to clarify that there is a difference. Fascial tissue and ligaments have a less elasticity than the other tissue. It has to be separated. And I want to express this by these sentences. And, therefore, this is indicated by the different figures. You see another elasticity for fascial tissue than for the organs, and so it has to be considered separately.
Q. So is that saying that the mesh -- strike that.
Is that saying that an appropriate mesh would have an elasticity of less than 10 percent for fascial tissue?
A. From this study, there -- this study confirms that an elasticity of less than 10 percent may be in the right range. But it is not sufficient just to take this study and make it like this and expect that everything is perfect.
Q. Okay.
A. But the range covers what I expect to be.
Q. And then it says, and 15 greater 100 percent for vaginal tissue.

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Is that a typo there or am I reading this wrong? What does that mean, 15 greater than 100 percent for vaginal tissue?

A. If you look to the original article of these two, there is -- in one study there is the measurement of 15 percent, and in the other study there is I think the study of corpses or so. There is -- they indicated that there is an elasticity of more than 100 percent. So you have to go in the detail to explain.

And I just mentioned what I -- what you can found in the literature, that there is this figure of 15 percent and 100 percent, which is extreme much there. But in this sentence, the intention was to show the difference, less than 10 percent for the more stiff tissues and more than 15, 20 percent for the more flexible tissues. You have different tissues. You want to reinforce different tissues, and, therefore, the device has to consider this one. And this is not written to partly discuss whether 100 percent is reasonable or not, and we have to go to the study.

Q. Doctor, if you've already said this, then I apologize.

But what is the range of elasticity

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that you would like to see for mesh placed for vaginal tissue?

MR. ANDERSON: Objection.

Go ahead.

BY MR. BROWN:

Q. A percentage, if you could, Doctor?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Well, vaginal tissue, just for reinforcement in direct contact with the vaginal tissue, the best data I found there derived from this study from Cosson. This is -- it starts from 20 percent, can go up to 100 percent.

BY MR. BROWN:

Q. So, Doctor --

A. But you have to consider that it is not done by measuring the elasticity of the textile. You have to look at the elasticity after tissue integration.

Q. So is it your testimony that the -- well, let me ask you this.

What is the optimal elasticity for a mesh in the pelvic floor? And if you can provide a range of percentages, that would be good.

MR. ANDERSON: Elasticity of the

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mesh?

MR. BROWN: Yes.

MR. ANDERSON: Okay.

THE WITNESS: I have to rely on this -- these anatomical biomechanical studies. And then I, from my point of view, a range of -- yeah. At least more than 20 percent stretchability. But maybe it's 30, 30 to 50 percent stretchability of a textile may be a good starting point to optimize it.

BY MR. BROWN:

Q. Doctor, do you believe that the elasticity of the Prolift® is adequate for use in the pelvic floor?

A. The elasticity of the Prolift® at a strain of -- let me see to the data, if I remember correctly. Does anyone have the page?

MR. ANDERSON: Do you have the elasticity open for Prolift®?

BY MR. BROWN:

Q. Are you saying that it's in your report somewhere?

MR. ANDERSON: I don't remember. I can look through it.

MR. RESTAINO: Page 21.

MR. ANDERSON: Is that a percentage,

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though?

MR. RESTAINO: Percentage, no.

THE WITNESS: No, no. Page 30 under 4.9 newton per centimeter of strength, elongation of 50 percent in the warp direction and 22 percent in the cross direction. The textile porosity and so on decreased, and effective porosity completely disappeared at a load of 4.9 centimeters.

So for the arm, the elongation is 22 percent, 25 percent and 27 percent respectively. The elongation is higher there. From these data alone, I would think that the capability to -- for elongation of the Prolift® is not the most serious problem of this device.

BY MR. BROWN:

Q. Do you believe that the elasticity of the Prolift® mesh is adequate for placement in the pelvic floor?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: The elasticity in its textile form fits the range, yeah. Is in the range I would expect that is appropriate for a textile.

- - -

(A discussion off the record

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occurred.)

- - -

BY MR. BROWN:

Q. Doctor, have you heard the term "bidirectional elasticity"?

A. I've heard it, yeah.

Q. Doctor, does the Prolift® have bidirectional elasticity?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: If you understand by this term in comparison to a plate of steel, which does not have any elasticity in either direction, that you just want to express that if you have a piece of Prolift® mesh there, that you tear it in one direction --

MR. ANDERSON: Tear or stretch?

THE WITNESS: Stretch. If you stretch it in one direction, that you get some certain elongation, and then afterwards, you can turn it around by 90 degrees, stretch it again and then get another elongation. If you mean this as bidirectional elasticity, I would say that Prolift® has this capability of bidirectional elasticity, as every mesh I know.

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BY MR. BROWN:

Q. And the way that you defined bidirectional elasticity, is that an appropriate way to define bidirectional elasticity?

A. I cannot answer the way or what is appropriate definition of this term, as I even did not get sufficient information by the FDA or by the reports from Ethicon what is meant by this term of bidirectional elasticity. Therefore, I do not know.

So in the definition I gave to you, I think this is a statement I can agree.

Q. When you say it's a statement you cannot agree --

A. I can agree.

MR. ANDERSON: That he can agree.

MR. BROWN: Oh, I'm sorry. Okay. Got you.

BY MR. BROWN:

Q. Doctor, let me ask you this, too.

When Ethicon stated that the mesh adapts to the various stresses of the body, are you able to --

A. What, that Ethicon stated?

Q. In the instructions for use, there's a statement that says that the mesh adapts to the various stresses of the body.

Are you able to say if the Prolift® adapts to the pelvic floor region?

A. I'm not able to understand this sentence, because I don't know what it means to adapt. Is it an active process or...

Q. Doctor, I can only use the word that's in the IFU, so --

A. Yeah. But you asked me to explain the sentence you put in there, so to adapt is an active process. To my knowledge, polymer is a dead substance, as taken for some bags. There is no active process of optimizing, growing, changing, so something like this. So adapt, the active process of adaptation to some strain by polypropylene, I do not understand this.

Q. Let me ask it in a different way.

Does it comply with the various stresses in the pelvic floor, the Prolift® mesh?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Comply means? Again, please help me to understand what is the definition of -- so compliance means a certain elongation at a certain strain. That is the definition of compliance.

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Of course you can measure the compliance of the Prolift® mesh. And if you consider different strains, you can look in the figure, and then you know the specific elongation at a strain. Therefore, you can define the compliance. But you can measure it for steel as well, so...

Again, I have some problems to understand this sentence.

BY MR. BROWN:

Q. That's fine. We're going to move on from there. Let me ask you a couple questions.

Doctor, can you say that the contracture rates for Prolift® lead to pain in a patient?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I know that contraction -- scarry contraction of a device is associated with clinical complications. I know this. I cannot answer it for a single patient. Yes.

BY MR. BROWN:

Q. Can you say what percentage of contracture leads to pain in a patient when a mesh

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is put in for pelvic floor?
A. For me there is no way to give an absolute number of the number of -- the percentage, how many are caused by. I only can say that there is, without any doubts, there is an increased risk to -- for manifestation of complication.
Q. Is there a safe range of contracture in the pelvic floor?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Safe contraction --
BY MR. BROWN:
Q. Do you want me to restate it? Would that be helpful?
A. Please.
Q. Sure. Is there a range of contracture that can take place in the pelvic floor that you would expect it not lead to an adverse event for patients?
A. From my experience and from my knowledge, it is almost impossible to define an absolute range where you can be, again, safe there. What we have learned during all these years is that you have a changed risk, that you can't change the risk with the -- by the selection of your material,

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and you can have an increased risk or you can have a lowered risk. But to go down to zero risk, I think this is not imaginable for me in no part of surgery.
Q. Is there a range of contracture that you would say leads to minimal risk for contracture in the pelvic floor?
MR. ANDERSON: Objection.
BY MR. BROWN:
Q. I'll restate it then.
Is there a contracture range for meshes that leads to minimal adverse events in a patient for pelvic floor repair?
A. I'm sure if you are looking, the well healing patients, then you will find a lower degree of shrinkage in these patients than if you're looking to the, let me say, bad healers in these. There you will see a higher degree of shrinkage. But, again, it will be impossible to define absolutely numbers for this.
Let me raise another aspect. We have made this evaluation of explanted mesh materials, and we have investigated different materials. And there has been several real large pore meshes. In the presence of a bacterial infection, even in these good meshes, large pore meshes, you have an

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intensified bridging and shrinkage. So it is impossible to give an absolute range there for me.
Q. Is there a mesh contracture today that you're aware of that provides lower contracture rates than the Prolift®?
MR. ANDERSON: Objection.
THE WITNESS: I don't know any comparative study in this regard.
BY MR. BROWN:
Q. Doctor, we're getting there. Let me ask you this real quick.
Your definition of inert?
A. Inert, I'm sure it's somewhere written, that there is no change after incorporation in a body or in human tissues, that there is no change of appearance and construction and chemical composition. That may be a term.
Q. Do you believe today that the poly -- scratch that.
When did you come to believe that the Ethicon polypropylene was not inert?
A. When I saw for the first time the electron microscopic images showing that you have this cracking at the surface by Clave and confirmed by the group around Ramshaw. That was the first

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indicating that it is probably not inert.
Q. And is there a difference between physical inert, chemical inert and biological inert?
A. I'm not aware for our -- in our field of research. The inertness has to consider the integration into the tissue, the integration with macrophages, with all these substances there. You may define it otherwise, just looking to the ultraviolet light, whether it is able to make a degradation. Maybe you define this as a physical inertness, but what is relevant for us is only what happens after integration in the body and not what happens in the package.
- - -
(Deposition Exhibit No. Klinge-21, Gynecare Prolift Instructions for Use, Bates stamped ETH.MESH.02341454 through ETH.MESH.02341459, was marked for identification.)
- - -
BY MR. BROWN:
Q. Last document, last line of questions.
A. It's a promise.
MR. ANDERSON: I heard it.

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MR. BROWN: That was off the record.
BY MR. BROWN:
Q. Doctor, this is the IFU of the Prolift®.
I think you've probably seen that before; is that correct?
A. I've seen it before.
Q. Do you have any opinions that you intend to offer at trial that are critical of this information for use in the Prolift®?
A. I didn't get it.
Q. Do you have any opinions that you intend to offer at trial that are critical of what's in this IFU?
A. Maybe again, or louder, or --
Q. Sure, sure. Do you have any opinions that are critical of this IFU, statements in the IFU?
A. So we have to go page by page or sentence by sentence --
MR. ANDERSON: Yep. Yep.
THE WITNESS: -- to go there.
MR. ANDERSON: Take your time, please.
THE WITNESS: Shall I, when I get to

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a sentence that I -- shall I raise it?
BY MR. BROWN:
Q. That's fine.
A. Of course? Otherwise, it is maybe --
Q. Yeah.
A. So "this material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use."
Q. Can you just tell me where you are before you start reading?
MR. ANDERSON: This page, second page under "GYNECARE GYNEMESH PS."
BY MR. BROWN:
Q. Okay.
MR. ANDERSON: Starting with, "This material."
BY MR. BROWN:
Q. Okay. When it's talking about retaining its strength indefinitely, is that the testimony you gave with regard to degradation?
MR. ANDERSON: Well, let him address that sentence.
BY MR. BROWN:
Q. Go ahead then.
A. So that is one concern, that retain

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its strength indefinitely, that this is likely not true.
The other is that you say, "When used as a suture has been reported to be nonreactive." That indicates I think not the true relationship between the polypropylene material and the tissue reaction as it is experienced with the meshes, because I think it is not justified to compare the tissue reaction to a suture to the tissue reaction to a mesh. This is just for this sentence.
Q. Go ahead.
A. So the next sentence, "The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth." Excellent strength indicates that it is optimized for the physiological requirements, and I didn't see this confirmation that it was optimized to fit to the physiological requirements.
"With sufficient porosity for necessary tissue ingrowth," that is correct. You have tissue ingrowth, but this does not meet the critical point. And, therefore, sufficient porosity indicates a maybe -- or indicates a misleading aspect for the consumer.
The assumption that it is

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approximately 50 percent more flexible than standard Prolene®, it will be necessary to look to the data available. So in the moment, I'm not able to really verify whether this is true in particularly in the physiological range. So what does it mean? But I think it is not the most critical part for me.
"Provides for elasticity in both directions," that is true.
"This construction permits the mesh to be cut into...desired shape or size without unraveling." That is true, that is an advantage of all knitted things, but it does not reflect the critical point. So maybe it would be helpful to say that trimming should be done outside or with a covering or something like this if you are aware whether this is a huge amount of material there.
Yeah. "Allows adaptation to various stresses encountered in the body." "The bi-directional elastic property allows adaptation to various stresses encountered in the body" indicate some active process. As I said, I cannot understand this one.
And also "PERFORMANCE," there is, again --
MR. ANDERSON: Did you hear what he

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said? Under "PERFORMANCE."
MR. BROWN: Got it.
THE WITNESS: So "Animal studies show that implantation...elicits a minimum to slight inflammation reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue." I think this sentence does not reflect the problem that might occur if you -- when you get a foreign body reaction with this size, with this surface for such a long time in a contaminated field. So all this -- all these aspects that may be a reason for concern, that is not mentioned in this sentence. And, thus, I think it gives a insufficient impression of what can be expected.
"The mesh remains soft and pliable." If you just see -- if you have ever seen one of these explanted meshes packed into this fibrotic tissue, then you know that this can never be a general statement, that the mesh remains soft and pliable.
"Normal wound healing is not noticeably impaired." I think this is not true. It is an additional burden for some patients, at least

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for some patients, which leads to a collapse of their local wound healing, leading to some complications at least for some, compromises.
"The material is not absorbed." I would accept -- I would agree in a certain time point, there is no complete absorption to this. But, you know, I think it is -- I wonder whether this is helpful.
Not "subject to degradation." I think this is, from my point, less likely than not. I hope I placed the "it" correctly.
MR. ANDERSON: It's less likely than not that this is true.
THE WITNESS: Okay.
MR. ANDERSON: All right.
THE WITNESS: "Or weakening by the action of tissue enzymes."
MR. BROWN: Just so it's not you testifying, let me just make sure.
BY MR. BROWN:
Q. When you said "less likely than not," does that mean less likely than not true?
A. It is more likely than not that it's going to be degraded over time.
"CONTRAINDICATIONS," I -- if I --

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when I look to all these references and literature and reports, I got the impression that there should be more contraindications, but that is not my field where I wanted to point out that some patients should be mentioned there, but you asked me my comments about this IFU. I think contraindications, that is a point for this.
"Acceptable surgical practices should be followed in the presence of infected or contaminated wounds."
Q. Let me just make sure, too, so that you're -- you know what my question is, is that these are aspects that you're going to testify that's critical to the IFU.
MR. BROWN: So if there are places you're not going to have him testify, Ben, then he doesn't need to go through that.
MR. ANDERSON: I was going to ask you that, but I didn't want to feel like I was directing.
So other than the contraindications, the warnings and precautions -- okay. Better question.
Is there anything in the "ADVERSE REACTIONS" section that you have any criticism or

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concerns about?
MR. BROWN: Fair enough. Let me ask it.
MR. ANDERSON: You ask it.
BY MR. BROWN:
Q. What I want to know is anything that you're going to testify to that is critical to the IFU.
So do you have any concerns with regard to the "ADVERSE REACTIONS" section in the IFU?
MR. ANDERSON: So in other words, just direct your attention to those two bullet points under "ADVERSE REACTIONS."
THE WITNESS: So not any longer "WARNINGS AND PRECAUTIONS"?
MR. ANDERSON: Right. Just "ADVERSE REACTIONS." Just read those.
THE WITNESS: Not this one?
MR. ANDERSON: No, no. Well, unless you see something.
BY MR. BROWN:
Q. Doctor, if you plan on testifying critical about this IFU, then you are welcome to discuss it at this time.

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MR. ANDERSON: Well, I'm going to not ask him about any criticisms under "CONTRAINDICATIONS" and "WARNINGS AND PRECAUTIONS." I'm going to leave that to the urogyns. I'm going to ask him, though, if he has any issues with regard to the "ADVERSE REACTIONS" section.

BY MR. BROWN:

Q. Doctor, do you have any concerns or critiques with regard to the "ADVERSE REACTIONS" section of the IFU?

MR. ANDERSON: In fact, I'm not going to ask him about "ADVERSE REACTIONS" either. That's really a urogyn field. I don't think that's appropriate.

So we're done. I got one question or two. Okay?

MR. BROWN: Let me just ask very quickly.

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(A discussion off the record occurred.)

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MR. BROWN: I am going to have to keep the deposition open, because there's a thousand explants, and so we can go down that at a later

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date.

MR. ANDERSON: All right. And I'll just object to any more questioning of Dr. Klinge other than if, with this rolling production that we're getting and these promises of Norderstedt documents, if I were to show those to him or anything arises as a result of documents that you asked me to produce that I actually agree to produce and that raises any new opinions or something that may give rise to something that would not be fair to, let's say, blind side you with at trial, although I wouldn't try to do that, anything that would come as a surprise to you that you haven't had a chance to fully evaluate with him, under those circumstances, then there may be the need to reopen his deposition. But, otherwise, we're done, with those clarifications by both of us. I just have a couple of questions for him.

MR. BROWN: All right.

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EXAMINATION

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BY MR. ANDERSON:

Q. Dr. Klinge, do you recall yesterday when Mr. Brown asked you this question, "Doctor,

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you're not an expert how mesh specifically leads to complications in pelvic floor repair; is that correct?"

Objection by me.

You said, "I don't think so, no."

Do you remember when he asked you yesterday the question, you're not an expert how mesh specifically leads to complications in pelvic floor repair? Do you remember that?

A. I remember that.

Q. What was your understanding as to what he was asking you?

A. My answer referred to his sentence, am I correct, that you are not an expect -- please, let me have --

Q. "Doctor, you are not an expert how mesh specifically leads to complications in pelvic floor repair?"

A. Okay. So the next sentence, "is that correct," your assumption that I am not an expert, and so was my understanding of this phrase. And, therefore, I answered with "no," you are not correct when you say I am not an expert, because I believe that I'm an expert on the topic complications to meshes and complications to meshes that have been

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used in the pelvic floor as well.

Q. Okay.

A. So, therefore, I never wanted to say that I have no expert knowledge in this field, but I was just referred to your sentence, "am I correct." And from my logic, therefore, no, you haven't been correct, to make it clear.

Q. Just to clear it then, Doctor.

Do you consider yourself an expert in the complications or injuries of surgical mesh in the pelvic floor, including the Prolift®?

A. I'm, of course, not an expert in doing the surgery or to avoiding some intraoperative complications, but, of course, I have expert knowledge about the late or the consequences, what happens after implantation of a textile structure.

Q. In the pelvic floor?

A. In the pelvic floor.

MR. ANDERSON: Thank you. No further questions.

MR. BROWN: Okay.

(Deposition adjourned at approximately 5:30 p.m.)

CERTIFICATE

I, ANN MARIE MITCHELL, a Notary Public and Certified Court Reporter of the State of New Jersey, do hereby certify that prior to the commencement of the examination, PROF. DR. UWE KLINGE was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____
ANN MARIE MITCHELL, CRR, RDR, CCR
Notary Number: 2356252
Notary Expiration: February 22, 2017
CCR Number: 30XI00212000

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After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,______________________, do hereby certify that I have read the foregoing pages, 274 - 523, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
PROF. DR. MED. UWE KLINGE DATE

Subscribed and sworn
to before me this
_____ day of _______________, 20____.
My commission expires:_______________

____
Notary Public

LAWYER'S NOTES

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